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CYTOMORPHOLOGICAL STUDY OF PALPABLE BREAST LUMPS BY FINE NEEDLE ASPIRATION CYTOLOGY

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LIST OF ABBREVIATIONS

FNAC – Fine Needle Aspiration Cytology
IAC – International Academy of Cytology
ADH – Atypical Ductal Hyperplasia
DCIS – Ductal carcinoma In-Situ
LCIS – Lobular carcinoma In- Situ
IDC (NOS) – Infiltrating Ductal Carcinoma (No Special Type)
TDLU – Terminal Duct Lobular Unit
WHO – World Health Organization
PT – Phyllodes Tumor
NPV – Negative Predictive Value
PPV – Positive Predictive Value
ROSE –Rapid On Site Examination
CB – Cell Block
SBR – Scarff Bloom Richardson
ml – milliliter
H&E – Hematoxylin and Eosin
TP – True positive
TN – True Negative
FP – False Positive
FN – False Negative
AFB – Acid fast bacilli
N:C – Nucleus:Cytoplasm
OPD – Out patient department
C1-C5 – Code 1 to Code 5

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INTRODUCTION

Breast carcinoma is one of the most life-threatening carcinoma in women and is the leading cause of death among women all over the world.[1]In India, the estimated mortality rate is about 12.7 per 100,000 women.[2] There are many causes for the increase in cases of breast carcinomas, some of which are due to late marriage, child birth at a later age, a short period of breast feeding and nulliparity or low parity etc.[3]

Palpable mass, mastalgia, and nipple discharge are some of the breast symptoms for which patients seek medical attention and the commonest one being breast lump. Although not all breast lesions are malignant, concern remains with the patient as well as the treating physician to rule out carcinoma.

In recent times, accurate diagnosis of breast lesions is made in 99% of cases by the 'Triple 'Test', which is a combination of clinical examination, mammography and, fine-needle aspiration cytology (FNAC).[4] Although the gold standard test for diagnosis is Histopathological examination, FNACs, especially in the hands of experienced cytopathologists, have high diagnostic accuracy, as high as 98.9% in some series.[5]

FNAC is a simple, noninvasive, cost-effective outpatient department procedure
The application of FNAC was first introduced by Martin and Ellis in 1930.[3]
It was then introduced in Europe in the 1950s by Lopez-Cardozo in the Netherlands and Soderstorm in Sweden. However, until 1980, it failed to gain importance. Then over a period of time, the technique became standardized and is now being utilized in diagnosing a number of conditions.[6]

The method is considered a rapid, reliable, and safe diagnostic tool to distinguish non-neoplastic from neoplastic breast lesions. Using ultrasound or stereotactic guidance, FNAC has an important role in diagnosing both palpable and nonpalpable lesions. The FNAC report plays a significant role as it decides further management of the affected patients as to whether to proceed with more invasive diagnostic methods or do appropriate surgical treatment.[7]

Complete knowledge of the clinical history, physical examination, imaging, and other laboratory tests is a must for a pathologist before performing FNAC. Clinical data serves as a safeguard in interpreting the cytology, and this should not bias the pathologist.[8]

FNAC procedure is done using 25 or 27 gauge needles. The ideal aspirate has a creamy consistency, which is due to high cell content in a small amount of fluid and remains inside the needle. The pathologists should take appropriate care to avoid injury or any other complications to the patient.[8]

The three main areas where FNAC plays a major role in the assessment of breast lesions are the following: (a) diagnosis of benign disease in symptomatic palpable lumps as part of triple assessment; (b) staging of breast carcinoma, in particular, preoperative axillary lymph node FNAC and intraoperative sentinel node imprints; and (c) diagnosis of metastatic disease at distant sites following treatment for carcinoma.[9]

It is emerging as a valuable tool in the preoperative assessment of breast masses, as it shows high sensitivity, specificity, and accuracy. One of the primary goals is to differentiate benign from malignant lesions. Nevertheless, in certain instances, this differentiation is not possible due to significant overlap on smears (in cases of fibroadenoma and proliferative breast diseases and atypical hyperplasia and low-grade carcinoma in situ, or papillary lesions) and also when there is a paucity of cells.[10]

A standardized approach is needed to improve training and performance of FNAC, smear-making techniques, and structured reporting will enhance the quality and reproducibility of reports across the globe, thus providing a basis for quality assurance measures which will help in improving patient care as well as for facilitating research purposes. Linking cytology reports to management algorithms will increase the use of ancillary tests for prognostic testing.[11]

There are many reporting systems for Breast FNACs. Currently, the IAC (International Academy of Cytology) system of reporting has been gaining much relevance. IAC Breast Group members who attended the Yokohama International Congress of

Cytology discussed regarding the use of a 3- or 5-stage coding system. This standardized reporting system includes five categories from C1 to C5.[12]

C1- Insufficient material

C2 - Benign

C3 - Atypical, probably benign

C4 - Suspicious, probably in situ or invasive carcinoma

C5 - Malignant

Although it is a relevant and non-invasive method to diagnose breast cancer, due to certain technical problems such as limited cellularity, excessive air drying, and artifactual mechanical disaggregation, it can contribute to false-negative or false-positive diagnosis of malignancy respectively.[13] Despite some shortcomings of the reporting categories, FNAC, as part of the triple assessment, has proved its value in describing the findings most accurately. The diagnostic impact depends on the experience of the operator, quality of preparation, and diagnostic skills of the cytopathologist.[14]

The success of FNAC depends on four fundamental requirements:

1. Samples must be representative of the lesion investigated.
2. Samples must be adequate in terms of cells and other tissue components.
3. Samples must be correctly smeared and processed.
4. The biopsy must be accompanied by sufficient and correct clinical/radiological information.[8]

One of the major limitations of FNAC is differentiating atypical ductal hyperplasia (ADH) from ductal carcinoma in situ (DCIS) and DCIS from invasive carcinoma, which is necessary as it affects the 'patient's treatment.[13]

Other limiting factors include the inability to make a definitive diagnosis of low-grade carcinomas, such as tubular carcinoma or invasive lobular carcinoma, papillary and fibroepithelial lesions, and differentiate primary from metastatic carcinoma.[13] Despite various limitations, FNAC is still a promising method for diagnosing various breast lesions.

The present study aims to analyze various breast lesions using FNAC and to categorize them according to the IAC system of reporting.

AIMS AND OBJECTIVES

The proposed study entitled ""**CYTOMORPHOLOGICAL STUDY OF PALPABLE BREAST LUMPS BY FINE NEEDLE ASPIRATION CYTOLOGY**"" is carried out with the following objectives.

OBJECTIVES:

1. To study in detail about the various cytomorphological patterns of breast lumps by FNAC.

2. To study the socio-demographic distribution of patients presenting with breast lump.

3. To standardize the reporting of breast lesions according to IAC (International Academy of Cytologists) criteria.

4. To correlate FNAC findings with histopathology wherever possible.

REVIEW OF LITERATURE

Fine needle aspiration cytology (FNAC) is a basic diagnostic technique used to investigate superficial and deep swellings. In the mid-nineteenth century, Kun (1847) and Lebert (1851), and Menetrier (1886) discovered a technique of using needles to obtain cells and tissue fragments to aid in the diagnosis of malignant tumors.

This technique was also employed in isolating microorganisms; like Leyden in 1883, used this method to isolate pneumonic microorganisms. Grieg and Gray, in 1904, diagnosed trypanosomiasis in cervical lymph node aspirates from patients with sleeping sickness.[15]

The FNAC for breast aspiration was introduced in 1960s by Franzen and Zajicek at the Karolinska Hospital in Stockholm. Franzen was an oncologist. He introduced standard May-Grunwald Giemsa stains on air-dried smears to allow for the rapid interpretation. Inspite of their success, FNAC was not used widely until the 1980s.[16]

However, FNAC began to flourish in the 1950s and 1960s, when a group of European pathologists started studying thousands of cases each year. True fine needles for aspiration were first introduced by Lopez-Cardozo in the Netherlands and Soderstorm in Sweden. Since then this technique is being used in diagnosing a number of conditions.[8]

Fine needle aspiration cytology was initially used to confirm a clinical suspicion of local recurrence or metastasis of known cancer before performing any surgical intervention on the patient. Following success in this area, its usage was expanded on focusing preliminary preoperative diagnosis of all kinds of neoplastic processes, benign or malignant, in any organ or tissue of the body and also on definitive, specific diagnosis in inoperable cases. This method is applicable to superficial lesions in the skin, subcutis and soft tissues, thyroid, breast, salivary glands, and superficial lymph nodes.[8]

FNAC is becoming popular in the preoperatJive assessment of breast masses, as it shows high accuracy, sensitivity, and specificity. This is because of its faster and easier

approach, cost-effective, and the technique can be performed with minimal complications. To differentiate between benign and malignant lesions is one of the primary goals of FNAC.[13]

Breast cancer is the most common cancer among females worldwide. It has ranked as the number one cancer with an age-adjusted rate as high as 25.8 per 100,000 women and mortality rate of 12.7 per 100,000 women.[17] Hence the diagnosis of breast lesions in early stage is of utmost importance to prevent mortality and morbidity, which occurs most commonly due to malignant progression.

The glandular structure of the breast undergoes changes from puberty to pregnancy and menopause because of the hormonal effects. Benign lesions are common in younger age groups, while malignant lesions are common in older age groups. Breast lesions become palpable at or more than 2 cm in size. It can be non-palpable or sometimes felt by the patient as heaviness in the affected breast.[18] The most common presenting symptoms are breast mass, mastalgia, nipple discharge, etc. Sometimes the patients can be asymptomatic as well.

In recent times, 'Triple 'assessment' technique which combines clinical, radiological, and pathological evaluation of breast masses, is becoming one of the vital tool in the diagnosis of breast lesions.[13] The pathological evaluation involving FNAC is a sensitive, rapid, cost-effective and a safe method in the evaluation of palpable breast lumps. It is less traumatic to the patient and also provides an immediate report to the patient. Hence it is widely accepted method for analyzing various breast lesions.[19]

However, there are certain instances where the differentiation of benign and malignant lesions is not possible, and the reasons are many. One of the major reasons being cellular paucity or poor aspiration technique.[13]

In India, FNAC was first introduced in the early 1970s and has spread to different parts through formal teaching under the postgraduate curriculum in pathology and by conducting workshops and continuing medical education programs for pathologists, surgeons/physicians, and radiologists. FNAC is now practiced in all medical colleges, in big public sector hospitals, and even in private clinics and laboratories.[20]

Embryology:

The human breast is made up of parenchymal and stromal elements. Parenchyma forms a group of branching ducts that leads to secretory acini development, and the stroma is mainly composed of adipose tissue. The presence of these building blocks is recognized in the early embryonic stage of human development. The process by which ductal system and acini develop is known as branching morphogenesis. Even though it is initiated in the fetus, it pauses in early childhood until puberty which is when the hormones are triggered for further differentiation.[21] Under the influence of hormones, interactions between the epithelium and mesenchyme lead to differentiation of the prenatally developed rudimentary structure that ultimately leads to the formation of a mature mammary gland.[22]

By the end of the first trimester, a fully developed mammary bud penetrating into the upper dermis is observed. Two distinct populations of epithelial cells (central and basal) are identified.[23] By the end of 6 months of gestational age, a well-defined tubular architecture made up of fibroconnective tissue stroma is developed.[21] At this stage, the breast tissue is evident (Figure 1).

At term, glandular tissues with 15 to 20 lobes have been formed, each having a lactiferous duct. The skin and the fibrous suspensory ligaments of Cooper that anchors the breast to the pectoralis major fascia, thus providing support to the breast.[24]

Anatomy:

The anatomy of breast is useful in the application of benign, malignant lesions as well as lesions associated with lactating breast. The breast or mammary gland is covered by skin and subcutaneous tissue, which is anchored on the pectoralis muscle by Cooper ligaments. The functional unit is made up of two major components: the terminal duct–lobular unit (TDLU) and the large duct system. These lobules and ducts are spread throughout the background fibrous tissue and adipose tissue, making up the majority of the breast. The nipple is located superior to the inframammary crease and found along the midclavicular line and the fourth rib (Figure 2).[25]

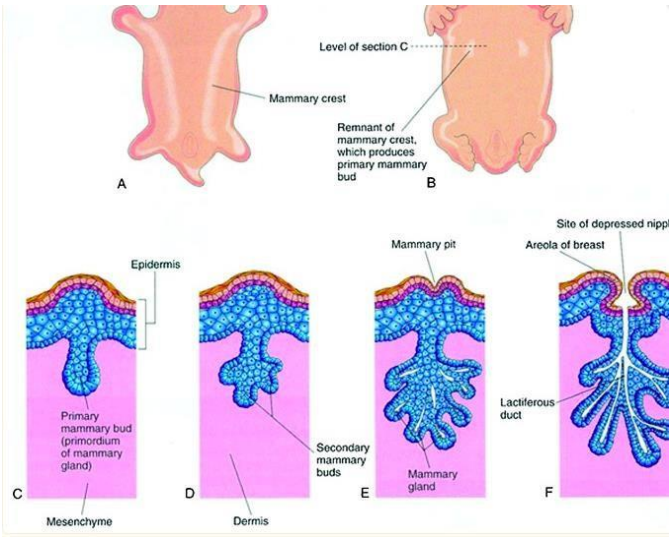

Figure 1: Schematic representation of the development of mammary gland

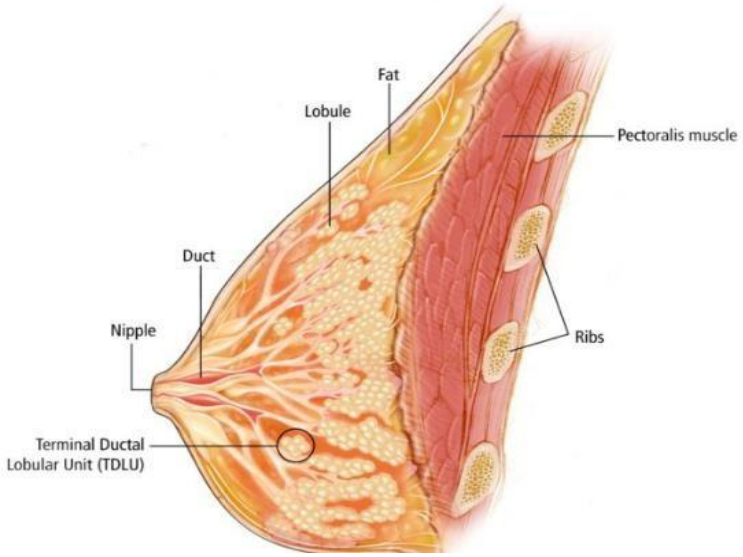

Figure 2: Structure of mammary gland[26]

The anatomical quadrants of the breast are Upper outer, Upper inner, Lower outer, Lower inner, and central (Figure 3). Their knowledge helps in locating exact position of the mass or lump during examination.

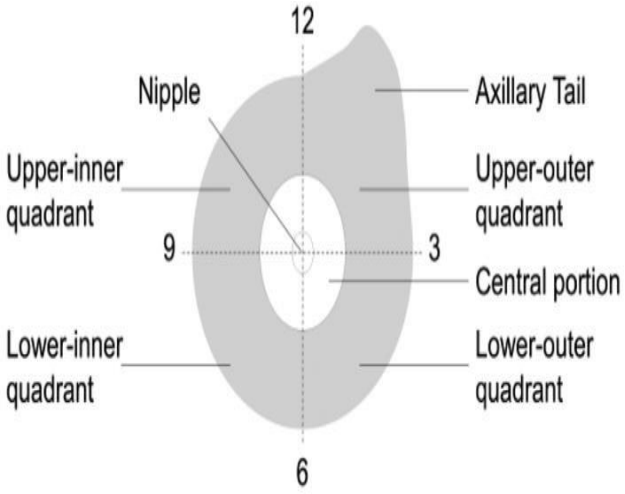

Figure 3: Anatomical quadrants of the breast[27]

Morphofunctional unit of breast is

i. Terminal duct-lobular unit (Acini+terminal ductule)(Figure 4)

ii. Large duct system

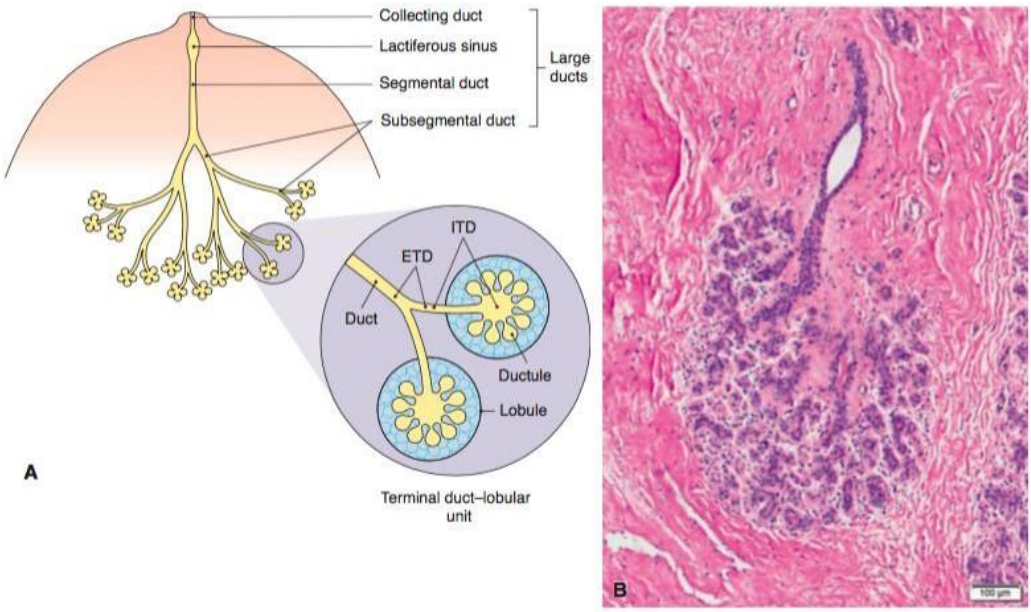

Figure 4:Terminal duct lobular unit[26] (A-Schematic representation B-Histology)

Blood supply:

Branches of the axillary artery, the internal thoracic artery, and some intercostal arteries supply the breasts.

- The axillary artery supplies blood via the superior thoracic artery, the pectoral branches of the thoracoacromial artery, the lateral thoracic artery and the subscapular artery.
- The internal thoracic artery supplies perforating branches to the anteromedial part of the breast.
- The second and fourth anterior intercostal arteries supply perforating branches more laterally in the anterior thorax.

Blood drains from the circular venous plexus around the areola and from the glandular tissue of the breast into the axillary, internal thoracic and intercostal veins via that accompany the corresponding arteries.

Nerve supply:

The anterior and lateral branches of the 4th to 6th intercostal nerves, which carry sensory and efferent fibres, supply the breast.

Lymphatic drainage:

Lymphatic drainage carries its importance in that the breast carcinomas spread through lymphatic vessels and hence increasing the chance of metastasis. Lymph node involvement also carries prognostic importance in managing breast carcinoma. Lymphatic channels form 'Sappey's plexus and collect under the areola. Lymph drains via the following nodes:

- Axillary lymph nodes drain about 75% and are divided into three levels according to their relationship with the pectoralis major muscle. (Figure 5)
  -Level 1 lymph nodes are situated laterally
  -Level 2 lymph nodes are posterior
  -Level 3 lymph nodes are medial to pectoralis major muscle
  The lymph node seen between pectoralis major and minor is called as 'Rotter's node.
- The internal mammary (parasternal) nodes (25% drainage) lie along the internal thoracic vessels.
- Some lymph from the breast also reaches the supraclavicular nodes, the cephalic (deltopectoral) node, the posterior intercostal nodes (lying in the front

of the heads of the ribs), the subdiaphragmatic and subperitoneal lymph plexuses.

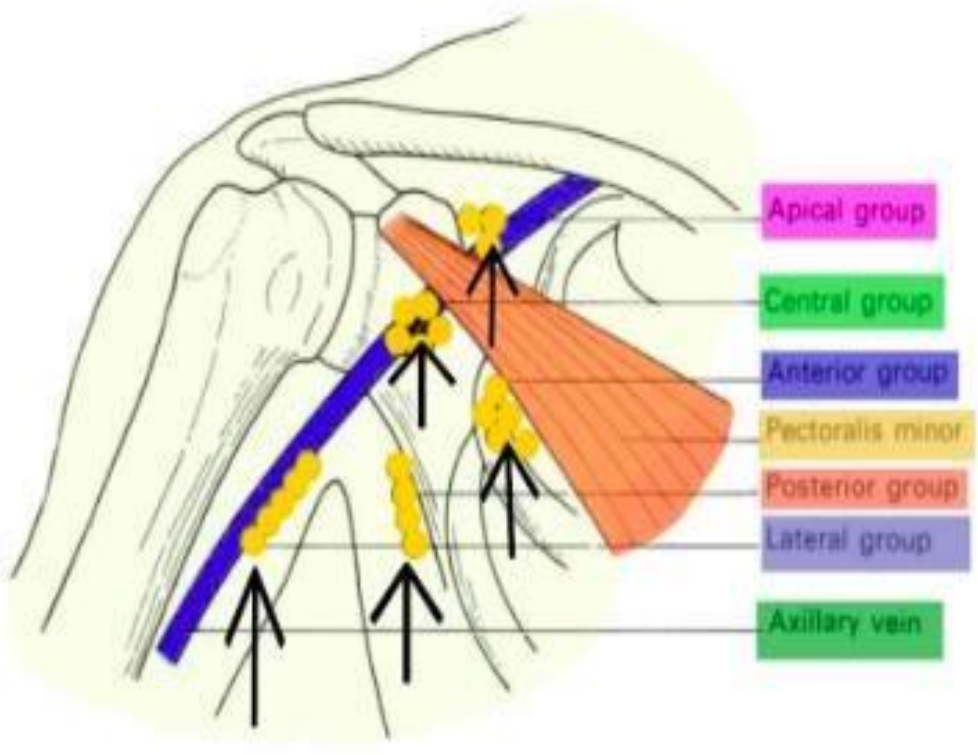

Figure 5: Lymphatic drainage of the breast

Microscopic features of various cells in normal breast aspirate[8]**:**

Glands are lined by the inner epithelial layer and outer myoepithelial layer
The Large ducts are tall columnar, whereas the small ducts and acini are cuboidal.

1. Epithelial cells:

-These are arranged in monolayer sheets with scanty cytoplasm.
-Nuclei are uniform, round to oval with smooth nuclear membrane.
-Nucleoli are inconspicuous.

2. Myoepithelial cells:

- They appear as naked with bipolar, dense and bland nuclei.
- No visible nucleoli are noted.
- Its presence is the hallmark of benign breast lesions.

3. Apocrine cells:

- They have abundant, finely granular cytoplasm.
- Nuclei is eccentric with fine chromatin.

4. Foam cells:

- Has abundant, multivacuolated cytoplasm.
- Cytoplasm may contain pigment inclusions.
- Nuclei are bland and round to oval in shape.

Classification of breast lesions[27]**:**

Breast lesions can be broadly classified into benign and malignant.

Benign lesions:

The benign breast lesions are grouped under the following

- Inflammatory conditions
- Cysts
- Fibroadenoma

The inflammatory conditions include:

1. Subareolar abscess
2. Granulomatous mastitis
3. Fat necrosis

Grey zone lesions:

- Papillary lesions
- Epithelial proliferative lesions
- Fibro-epithelial lesions

Malignant lesions:

- Invasive ductal carcinoma
- Invasive lobular carcinoma
- Mucinous carcinoma
- Tubular carcinoma
- Metaplastic carcinoma
- Invasive micropapillary carcinoma
- Apocrine carcinoma
- Breast carcinoma with osteoclastic giant cells
- Adenoid cystic carcinoma
- Metastatic malignancy

WHO Classification of breast carcinoma (5th edition, 2019)[29]

- Epithelial Tumors

- Invasive breast carcinoma
    - Infiltrating duct carcinoma NOS
    - Oncocytic carcinoma
    - Lipid rich carcinoma
    - Glycogen rich carcinoma
    - Sebaceous carcinoma
    - Lobular carcinoma
    - Tubular carcinoma
    - Cribriform carcinoma
    - Mucinous adenocarcinoma
    - Mucinous cystadenocarcinoma
    - Invasive micropapillary carcinoma of breast
    - Metaplastic carcinoma NOS

- Rare and salivary gland type tumors
    - Secretory carcinoma
    - Acinar cell carcinoma
    - Mucoepidermoid carcinoma
    - Polymorphous adenocarcinoma
    - Adenoid cystic carcinoma
    - Classic adenoid cystic carcinoma
    - Solid basaloid adenoid cystic carcinoma
    - Adenoid cystic carcinoma with high grade transformation
    - Tall cell carcinoma with reversed polarity

- Neuroendocrine neoplasms
    - Neuroendocrine tumor, NOS
    - Neuroendocrine tumor, grade 1
    - Neuroendocrine tumor, grade 2
    - Neuroendocrine carcinoma NOS
    - Neuroendocrine carcinoma, small cell
    - Neuroendocrine carcinoma, large cell

- Epithelial-myoepithelial tumor
- Pleomorphic adenoma
- Adenomyoepithelioma NOS
- Adenomyoepithelioma with carcinoma
- Epithelial-myoepithelial carcinoma

- Non invasive lobular neoplasia
    - Atypical lobular hyperplasia
    - Lobular carcinoma in situ NOS

    Classic lobular carcinoma in situ

    Florid lobular carcinoma in situ
    - Lobular carcinoma in situ, pleomorphic

- Ductal carcinoma in situ (DCIS)
    - Ductal carcinoma, non infiltrating, NOS
    - DCIS of low nuclear grade

- DCIS of intermediate nuclear grade
- DCIS of high nuclear grade

- Benign epithelial proliferations and precursors
  - Usual ductal hyperplasia
  - Columnar cell lesions including flat epithelial atypia
  - Atypical ductal hyperplasia

- Adenosis and benign sclerosing lesions
  - Sclerosing adenosis
  - Apocrine adenoma
  - Microglandular adenosis
  - Radial scar / complex sclerosing lesion

- Papillary neoplasms
    - Intraductal papilloma
    - Ductal carcinoma in situ, papillary
    - Encapsulated papillary carcinoma
    - Encapsulated papillary carcinoma with invasion
    - Solid papillary carcinoma in situ
    - Solid papillary carcinoma with invasion
    - Intraductal papillary adenocarcinoma with invasion

- Adenomas
  - Tubular adenoma NOS
  - Lactating adenoma
  - Duct adenoma NOS

- Mesenchymal tumors

- Vascular tumors

- Hemangioma NOS
    - Perilobular hemangioma
    - Venous hemangioma
    - Cavernous hemangioma
    - Capillary hemangioma
- Angiomatosis
- Atypical vascular lesion
    - Lymphatic atypical vascular lesion resembling lymphangioma
    - Vascular atypical vascular lesion resembling hemangioma
- Postradiation angiosarcoma
    - Epithelioid angiosarcoma
- Angiosarcoma
    - Epithelioid angiosarcoma

- Fibroblastic and myofibroblastic tumors
    - Nodular fasciitis
    - Myofibroblastoma
    - Desmoid type fibromatosis
    - Inflammatory myofibroblastic tumor

- Peripheral nerve sheath tumors
    - Schwannoma NOS
    - Neurofibroma NOS
    - Granular cell tumor NOS
    - Granular cell tumor, malignant

- Smooth muscle tumors

- Leiomyoma NOS
    - Cutaneous leiomyoma
    - Leiomyoma of the nipple and areola
- Leiomyosarcoma NOS

- Adipocytic tumors

- Lipoma NOS

- Angiolipoma NOS
- Liposarcoma NOS

- Other mesenchymal tumors and tumor-like conditions
  - Pseudoangiomatous stromal hyperplasia

- Fibroepithelial tumors
  - Fibroadenoma NOS
    - Phyllodes tumor NOS
    - Periductal stromal tumor
  - Phyllodes tumor, benign
  - Phyllodes tumor, borderline
  - Phyllodes tumor, malignant
  - Hamartoma

- Tumors of the nipple
  - Nipple adenoma
  - Syringoma NOS
  - Paget disease of the nipple

- Malignant lymphoma
  - Diffuse large B cell lymphoma NOS
  - Burkitt lymphoma NOS/Acute leukemia, Burkitt type
    - Endemic Burkitt lymphoma
    - Sporadic Burkitt lymphoma
    - Immunodeficiency associated Burkitt lymphoma
  - Breast implant associated anaplastic large cell lymphoma
  - Mucosa associated lymphoid tissue lymphoma
  - Follicular lymphoma NOS

- Metastatic tumors

- Tumors of the male breast
  - Gynecomastia

- Carcinoma
  - Invasive carcinoma
  - In situ carcinoma

FNAC findings in pathological conditions[8]

1. Fibrocystic breast disease:
   - Epithelial fragments with normal epithelial cells
   - There is presence of scattered single or bare bipolar/oval nuclei,
   - Background of variable amounts of cyst fluid, macrophages, and apocrine metaplastic cells can be seen.

2. Mastitis:
   - Inflammatory cells, could be acute or/and chronic.
   - Regenerative epithelial atypia is seen.
   - Epithelioid cells, histiocytes, multinucleated giant cells and plasma cells are present in the case of granulomatous mastitis.
   - Microorganisms represent infectious mastitis.

3. Breast abscess:
   - Purulent inflammation can be noted.
   - Keratin flakes and debris, along with mature squamous cells, are seen.

4. Fat necrosis:
   - Granular debris, fat droplets and fragments of adipose tissue are seen in a dirty background.
   - Foamy macrophages, multinucleated giant cells and adipocytes with bubbly/vacuolated cytoplasm can be seen.
   - Chronic inflammatory cells are usually present.
   - There is absence of epithelial cells.

5. Fibroadenoma:
   - Cellular smears with a bimodal pattern of epithelial and stromal

fragments

- Large, branching sheets of bland epithelial cells,
- Numerous single, bare bipolar/oval nuclei in the background.
- Fragments of fibromyxoid stroma are also noted.

6. Phyllodes tumor (PT):
   - The classic cytological features in PT are similar to fibroadenoma.
   - But, when compared to fibroadenoma, stromal fragments are larger, increased in number (stromal overgrowth) and are hypercellular (phyllodes fragments);
   - The single stromal cells in the background are plumper than the typical oval bare nuclei seen in fibroadenoma.

7. Ductal carcinoma in-situ (DCIS):
   - The grey zone areas of FNAC lie in differentiating low-grade DCIS from atypical hyperplasia.
   - Whereas high-grade DCIS is almost obviously malignant and reported as high-grade, the level of invasion is impossible to comment.
   - Features of high grade DCIS are:
     -Cell rich smears are usually present.
     -Neoplastic cells are seen singly, irregular sheets
     -Large pleomorphic nucleus seen
     -Necrotic debris, granular calcium, macrophages, and lymphocytes are seen in the background.

8. Lobular carcinoma in-situ (LCIS):
   - Moderately cellular samples
   - Tight or cohesively arranged atypical epithelial cells.
   - Mild nuclear atypia is seen.
   - The cells are small with prominent nucleoli.
   - Occasional cells have intracytoplasmic vacuoles.
   - However, distinction from lobular carcinoma may not be possible

without histological correlation.

9. Infiltrating ductal carcinoma- no special type (IDC- NOS):

    - Moderate tohighlycellularsmears
    - Singly lying population of epithelial cells; no myoepithelial cells, no single bare bipolar nuclei are seen.
    - Variable loss of cell cohesion – irregular clusters and single cells,
    - Single epithelial cells with intact cytoplasm,
    - Moderate to severe nuclear atypia enlargement, pleomorphism, irregular nuclear membrane and chromatin
    - Fibroblast and fragments of collagen (stromal desmoplasia) associated with the atypical cells.
    - Intracytoplasmic neolumina,
    - Necrosis unusual.

10. Tubular carcinoma:

    - Moderately cellular smears,
    - Cells predominantly in cohesive clusters,
    - Epithelial fragments with an angular or tubular shape,
    - Relatively uniform, mildly to moderately atypical epithelial cells,
    - Absence or paucity of single bipolar nuclei of benign type,
    - Fibroblastic cells; fragments of fibromyxoid or elastotic stroma.

11. Mucinous (colloid) carcinoma:

    - Abundant background mucin (recognizable macroscopically),
    - Atypical cells in small solid aggregates and single intact epithelial cells,
    - Mild to moderate nuclear atypia,
    - Benign epithelial cells and bipolar nuclei are absent,
    - 'Chicken 'wire' blood vessels.

12. Medullary carcinoma:

- Highly cellular smears,
- Poorly cohesive cells in clusters and single,
- Large, pleomorphic, obviously malignant nuclei with prominent nucleoli,
- Many lymphocytes and plasma cells.

13. Infiltrating lobular carcinoma:

    - Cells single and in small clusters,
    - single files characteristic,
    - Scanty cytoplasm; many naked nuclei; nuclear molding in cell clusters,
    - Small hyperchromatic nuclei of relatively uniform size,
    - Irregularity of nuclear shape with angular, triangular, indented or budding nuclei,
    - Intracytoplasmic Lumina/mucin vacuoles/signet ring cells, Few if any naked bipolar nuclei,
    - Thick, eosinophilic background with crushed material interspersed between fatty vacuoles and small fibrous stromal fragments.

14. Paget's disease of the nipple:

    - Backgroundofkeratin, squamous cells,
    - Inflammatory cells and debris (scrape smears from the nipple).
    - Large malignant cells, singly and in small groups, closely associated with squamous and inflammatory cells.
    - Abundant pale cytoplasm with distinct borders.
    - Obvious nuclear features of malignancy.

Literature survey:

In 2013, Vasu Reddy et al. performed a study on the cytological and histopathological correlation of breast FNAC and the sensitivity, specificity, and false negative values were 99%, 100%, and 1%, respectively.[30] Similarly, another study by Aaisha et al. in 2020 showed a sensitivity of 91.66%, specificity of 100%, positive predictive value (PPV) of 100%, negative predictive value (NPV) of 98% and accuracy of 98.4%.[31]

In 2020, Aamir et al. conducted a study analyzing cytomorphological patterns of breast lesions. Among 100 female patients with breast lesions, 54% of benign cases and 41% of malignant cases were obtained after histopathological confirmation. The specificity, sensitivity, NPV, PPV, and diagnostic accuracy of FNAC in this study were 100%, 91.11%, 98.18%, 100% and 98.96%, respectively.[32]

Studies on socio-demographic factors that included level of education, family income, locality and their analysis of breast cancer patients were done by Sarkar et el in 2020 and following were the observations. 26.4% were graduates, 61.3% had a primary/secondary education, and illiterate constitutes 13.6%. 80.6% were married, and 14.4% were unmarried. 25.7% were nulliparous 74% were parous women.[33]

Biju et al., in 2021, compared the utility of mammography and FNAC in diagnosing early breast cancer. They included 80 female patients with a palpable breast lump who were subjected to undergo mammography and FNAC and the results were confirmed by histopathological examination. Accuracy of mammography was 90% and that of FNAC was 96.25%.[34]

Agrawal et al. in 2021 conducted a study to see whether Rapid on site evaluation improved the sensitivity of Breast cytopathology by comparing it with histopathology findings. A total of 1,147 FNAC slides from September 2016 to December 2018 were retrieved, out of which 442 (38.5%) underwent ROSE and 624 (54.4%) histopathology. IAC reporting system was used and they recorded 4.9% inadequate, 65.3% benign, 7.8% atypical, 3.3% suspicious for malignancy, and 18.7% malignant lesions. The overall sensitivity and specificity for identifying in situ and malignant lesions were 99.1% and 99.3%, respectively, and these were improved by ROSE. Hence they derived that ROSE improved the concordance between cytopathology and histopathology from 76.9% to 90.2%, by reducing inadequate ($p < 0.001$) cases.[35]

Another study by Sowmya et al. correlated cytological findings of breast lesions with cell block (CB) and histopathological diagnosis. A total of 160 patients underwent FNAC of palpable breast lump/lumps. Cell-block preparation was done for 80 cases

and the histopathological examination was performed on all 160 cases. Out of 160 patients, on cytological examination, 107 cases (67%) were benign and 53 (33%) were malignant. On histopathological examination, 104 cases (65%) were benign and 56 cases (35%) were malignant. The sensitivity, specificity, positive predictive value and the negative predictive value were calculated as 94.5%, 100%, 100% and 97.01% respectively. The only discordance was with the diagnosis of proliferative breast disease with atypia in FNAC, which happened to be Invasive duct carcinoma on histopathology. On examination of cell block, two cases that were indeterminate in FNAC turned out to be malignant. The sensitivity and specificity for diagnosing breast lesions in FNAC and Cell block were calculated as 97.5% and 100%, respectively. The only discordance was with the diagnosis of proliferative breast disease with atypia in FNAC, which was reported as positive for malignancy on cell block. Hence they concluded that the difficulties incurred during the diagnosis by FNAC could be corrected by using cell-block, which makes the diagnosis easy and reliable.[36]

Prema et al. in 2020, studied the diagnostic pitfalls in FNAC by correlating them with histopathological findings. Cases that showed cytological and histological disparity were reevaluated to detect the possible cause of discrepancy. Their findings were as follows. For the diagnosis of carcinoma, the sensitivity was found to be 92.9%, specificity was 100%, positive predictive value was 100%, negative predictive value was 97.2%, and the total accuracy was 99%. False positives were not seen, and two cases were false negatives. Suboptimal material, lack of extensive sampling, and absence of all the characteristic features were the reasons for underdiagnoses, which were recognized as the common pitfalls.[37]

Aaisha et al. conducted a retrospective study of 125 cases. Out of these123 FNAC cases (98.4%) correlated with histopathology with a sensitivity of 91.66%, specificity of 100%, positive predictive value (PPV) of 100%, negative predictive value (NPV) of 98% and accuracy of 98.4%. They also compared their study with mammography findings. Out of 125 cases, mammographies of 25 cases were retrieved and derived sensitivity of 87.5% and specificity of 94.11% with a diagnostic accuracy of 92%. FNAC helps us to differentiate malignant from benign breast lesions with high specificity, sensitivity and accuracy. They had concluded that along with FNAC, employment of newer diagnostic modalities like immunohistochemistry,

mammography, and doppler in sonomammography might increase diagnostic accuracy.[38]

The major role of FNAC is to distinguish benign and malignant lesions. However, for prognostic information and treatment options, cytopathological grading system is essential. Several grading systems have been introduced for this purpose, and few studies have been conducted to analyze which grading system is appropriate and close to the Scarff-Bloom-Richardson (SRB) histological grading system.

In 2014, Cherry et al. analyzed and compared different grading systems used for the cytology of breast carcinoma. The study focused on cytomorphological features and the scoring criteria considered by various authors for reporting breast carcinoma. Also, their strengths, short-comings, and practical applicability were discussed. Nuclear cytomorphological features were important prognostic markers and have been considered by all the studies for grading breast carcinoma. According to this study, the grading system by Howell was the most appropriate and closest to the accepted Histologic grading system as it applies SBR histological grading system. They concluded that all breast FNAs from malignant lesions should include the cytological grading, especially in low-resource settings where core biopsy is not routinely performed for diagnosis, and the treatment is often based on the cytology report itself, as this will provide relevant predictive and prognostic information to the attending clinician and can assist him/her with better management of the patients.[4]

Kaushik Saha et al. in 2013 evaluated six grading systems, namely Fisher's, Mouriquand's, Robinsons, Howells, Khans, Taniguchis and compared with the histological grading system of Scarff Bloom Richardson (SBR)'s method. They concluded that among the six three-tier cytological grading systems, Robinson's system was simple, more objective, with minimal time and effort, reproducible and correlated precisely with SBR histological grading system.[4]

Also, Farook et al. in 2010 conducted a study comparing two cytograding systems, namely 'Robinson's and Mouriquand. A high degree of concordance was observed between the two grading methods (90.9%). But to conclude, Robinson's grading system

was easier and better because of a more objective set of criteria and easy reproducibility.[39]

Another study by Shirish et al. in 2017 also concluded that 'Robinson's cytological grading system was easy to interpret and correlated precisely with histological grading.

Recently used cytograding system is the IAC Yokahama reporting system, which was started in 2016. The IAC Yokohama Breast FNAC Reporting system was designed by a group of cytopathologists along with surgeons, oncologists, and radiologists. The motive for its development is to standardize reporting system, which will help to improve the interpretation of breast cytology. It also helps improve treatment options among clinicians by providing a quality report.
In 2021, Ahuja et el conducted a study on 554 breast FNAC aspirates to which 242 histopathological correlations were available. They categorized them according to IAC Yokohama Reporting System and the following were the results. They had 3.6% insufficient, 69.5% benign, 6.3% atypical, 2.3% suspicious, and 18.2% malignant lesions, respectively.[2]

In 2020, Panwar et al. studied 225 cases of FNAC, and the final cytological report was given according to the IAC coding system and obtained the following result. C1 in 03 (1.3%) cases, C2 in 186 (82.6%) cases, C3 in 13 (5.7%) cases, C4 in 04 (1.7%) cases, and C5 in 19 (8.4%) cases. The overall sensitivity and specificity were 100% and 97%, respectively.[12]

Through the literature surveys done, it is seen that FNAC has increased sensitivity and specificity in diagnosing breast lesions and that the most recently and popularly used IAC system of reporting plays an important role for both pathologists and treating physicians. Hence, this study analyzed the importance of both these and socio-demographic features.

MATERIALS AND METHODS

Study design:

Observational cross-sectional study.

Place of Study and Sample Frame:

The study was conducted at SANTOSH MEDICAL COLLEGE AND HOSPITAL, Ghaziabad, Uttar Pradesh. Patients were referred from Surgery department to Pathology section for FNAC, where the samples were collected.

Period Of Study:

The study was conducted for one year.

Study Population:

Females of all age groups requiring breast FNAC were enrolled in the study.

Inclusion criteria:

(1) All female patients with an unknown primary diagnosis of a breast mass.
(2) Patients consented to inclusion in the study according to the designed proforma.

Exclusion criteria:

(1) Patients with recurrent malignancy.
(2) Past or current chemotherapeutic or prevention treatment.
(3) Male patients with breast carcinoma and gynecomastia.

Sample size:

Complete enumeration of patients with complaints of breast lump following the inclusion criteria was enrolled for the study from January 2021 to December 2021.

Procedure:

A predesigned semi-structured questionnaire was prepared based on the review of literature on FNAC. A pilot study on 10 cases was done in order to understand the feasibility, reliability and validity of the questionnaire. After the pilot study, corrections were made to the questionnaire based on a further review of literature and advice/suggestions from the guide of the study. The final questionnaire was then used for data collection among the study participants.

After taking the 'patient's informed consent, participants were included in the study. A brief clinical history, general examination and local examination of breast were done to evaluate the signs and symptoms.

An FNAC tray consisting of 22-23 gauge needles, 10 ml syringes, sterile gloves, cleaned and dried glass slides, pre-injection swabs, sterile cotton and marker for slides were kept ready. (Figure 6)

After explaining the procedure, the patient was made to lie in supine position.
The lump was localized by palpation and cleaned with a sterile swab.
The swelling was fixed using the thumb and index finger of the left hand.
A 10cc disposable syringe with a 22 to 23-gauge needle was inserted into the mass and aspiration will be done under negative pressure.
A single point of entry with the multidirectional technique was used.
Once the material entered the hub of the needle, negative pressure was released, and the needle is withdrawn.
Immediate pressure was applied with a sterile gauze pad over the mass.
The material was expelled onto the slides, and with the help of another slide, smears were made with a single gentle sweep. The slides were air-dried, fixed with methanol and stained with Giemsa stain. (Figure 7) A few wet-fixed smears were taken and stained with H&E.

Figure 6: Tray for FNAC procedure

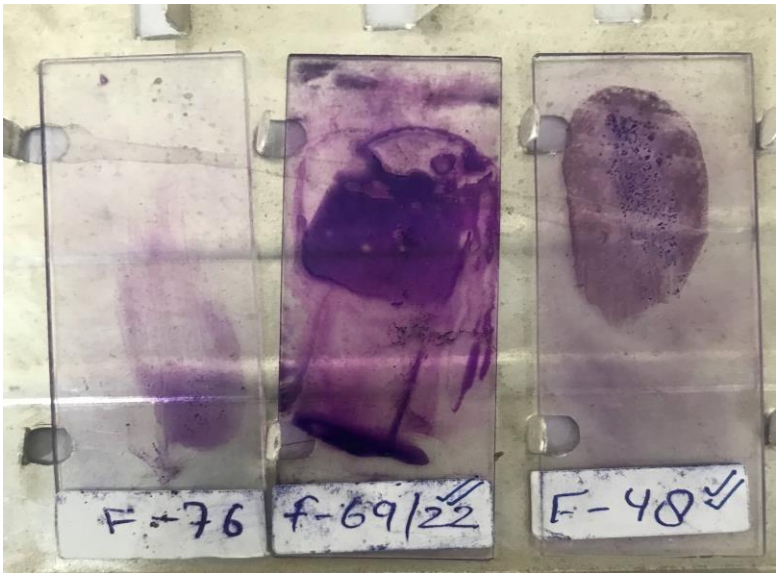

Figure 7: Giemsa stained FNAC slides

Cytological Interpretation:

(A) All the lesions were categorized into five categories, C1 to C5, according to the International Academy of Cytology (IAC) Yokohama reporting criteria.

C1 – Inadequate

C2 – Benign

C3 – Atypical, probably benign

C4 – Suspicious, probably in situ or invasive carcinoma

C5 –Malignant

(B) Further categorization was made using standard criteria from the literature for C2 category lesions.

(C) Histopathological correlation was made whenever the specimens were biopsied.

(D) The sensitivity, specificity, and positive predictive value, of fine needle aspiration as a diagnostic tool were calculated wherever biopsies had been performed based on these formulas.[40]

Sensitivity=TP/TP+FNx100

Specificity=TN/TN+FPx100

Positive predictive value=TP/TP+FPx100

Key:
TP-true positive
TN-true negative
FN-false negative
FP-false positive

RESULTS

The present study consists of FNAC material obtained from the breast lesions of 112 cases over a one year period at the Department of Pathology, Santosh medical college and hospital, Ghaziabad. The observations from the study are as follows.

Age Distribution:

The patients ranged from 13 to 75 years, with the median age being 30 years. The commonest age group was between 21 to 40 years (54.5%) followed by <20 years (25%), 41-60 years (16.1%) and >60 years (4.5%). (Figure 8)

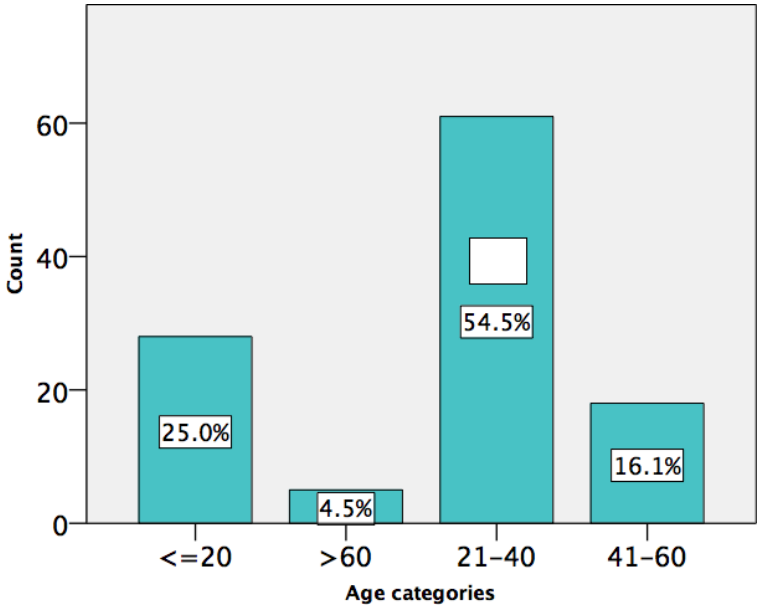

Figure 8: Bar diagram representing patients of various age groups

Socio-economic factors:

Being a tertiary care charity hospital situated in National Capital Region (NCR), a maximum number of patients around 73(65.2%) were belonging to an upper lower socio-economic group, followed by lower middle 34(30.4%)(Figure 9). About 104(92.9%) patients were from urban setup and 8(7.1%) were from rural areas (Figure 10). 89(80%) females were married and 23(21%) were unmarried (Figure 11). Maximum females (73, i.e., 65%) belonged to the parous category and the remaining 39 females (35%) were nulliparous. (Figure 12)

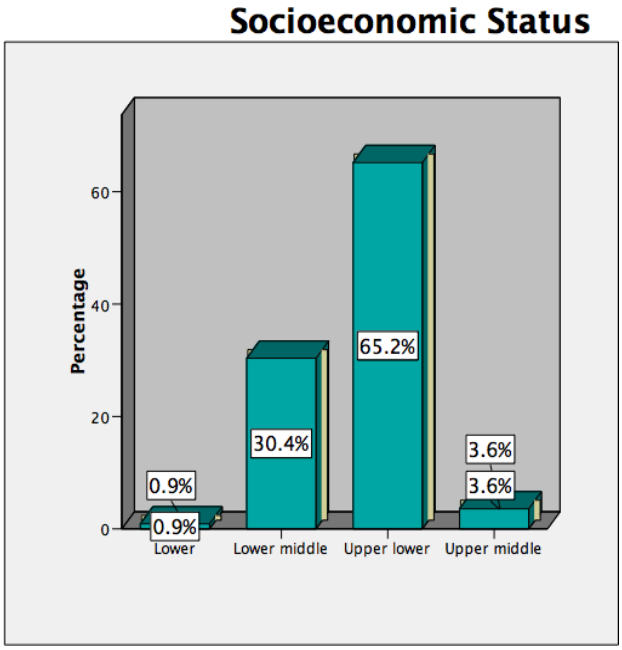

Figure 9: Bar diagram representing socio-economic status

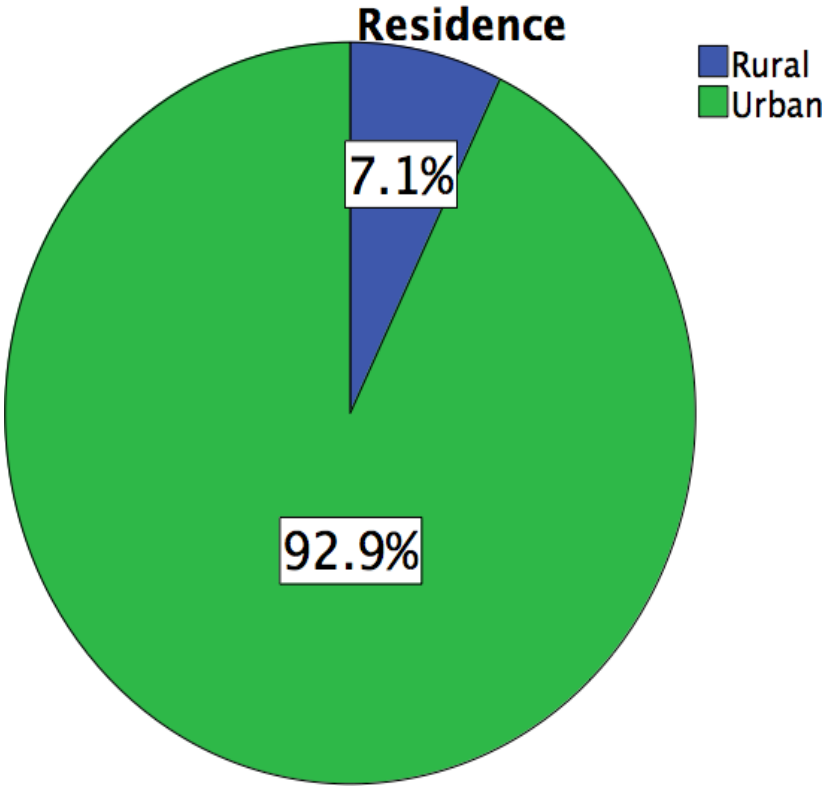

Figure 10: Pie chart representing residence of the patients

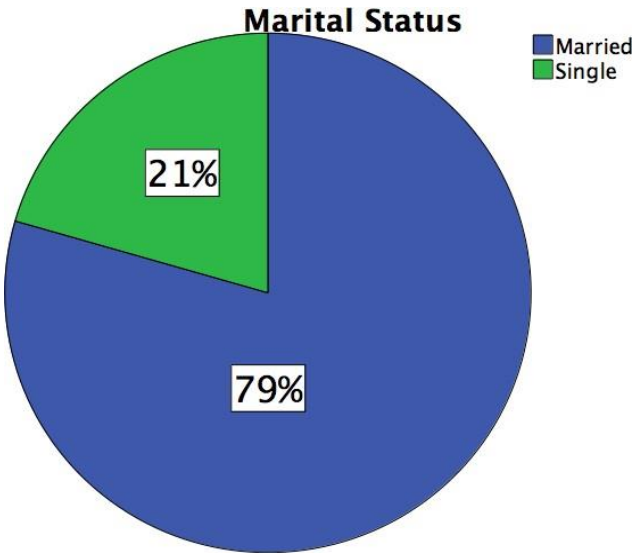

Figure 11 : Pie chart representing marital status of the patients

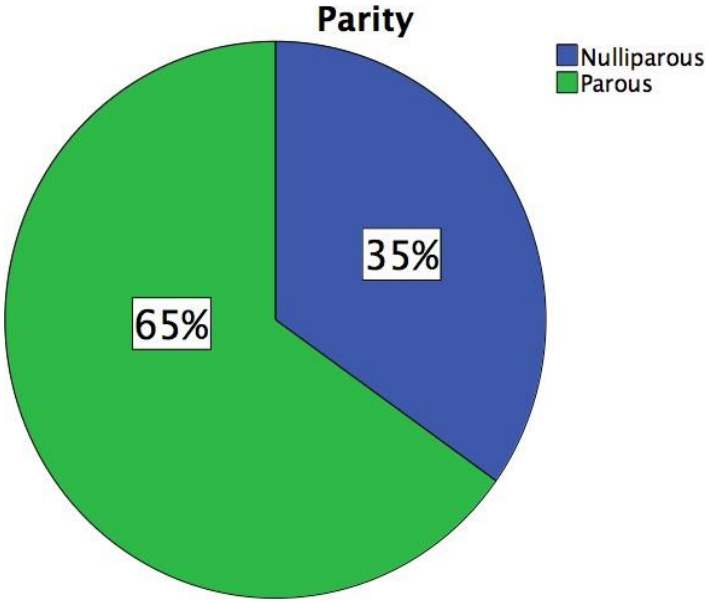

Figure 12: Pie chart representing parity status of the patients

Distribution of breast lesion in relation to right or left:

Out of 112 cases, 51% of cases were located in right breast, 45% in left breast and 4% were bilateral. (Figure 13)

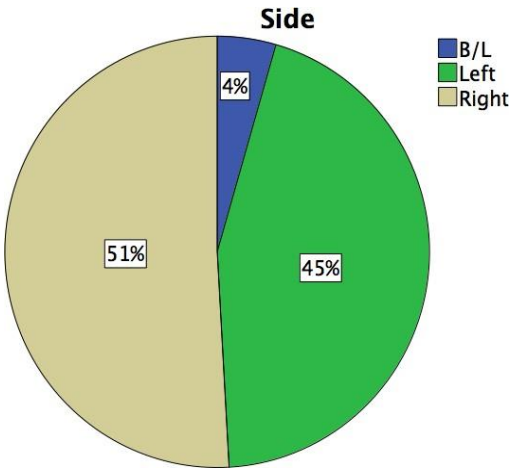

Figure 13: Pie chart representing laterality of the lesion

Presenting symptoms:

The most common presenting symptom was mass in the breast which was seen in 73 patients (65%), 17 (15%) patients presented with pain along with mass, 13 (12%) of them had only pain as their chief complaint, rest of the complaints with which patients presented were nipple retraction (0.9%) and nipple discharge (2%) (Table 1)

Chief complaints	No. of cases
Mass	73
Mass and Pain	17
Pain	13
Nipple Retraction	1
Nipple discharge	2
Pain and warmth	6

Table 1: Presenting symptoms and number of cases

Distribution of lesions according to anatomical quadrants:

Most common location of mass was in the upper outer quadrant at about 40%(45 cases), followed by the lower outer quadrant at 21%(24 cases), lower inner quadrant 19%(21 cases), upper inner quadrant 15%(17 cases). In 4 cases, the mass was diffuse and seen in all quadrants and 1 case was located in the subareolar region. (Figure 14)

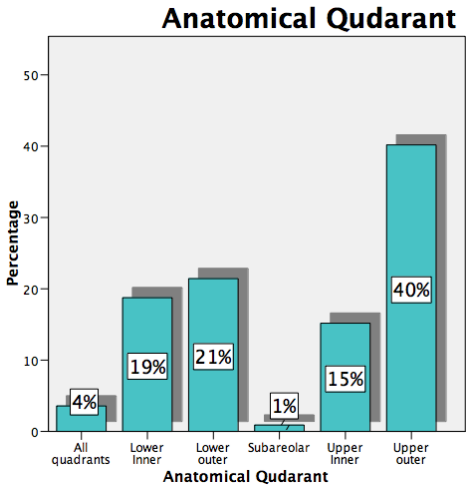

Figure 14: Bar diagram representing anatomical distribution of the lesions

Quadrant	Percentage	No. of cases
Upper outer	40	45
Upper inner	15	17
Lower outer	21	24
Lower inner	19	21
All quadrants	4	4
Subareolar	0.9	1
Total	100	112

Table 2: Anatomical distribution of lesions and their percentage

Adequacy of the aspirate:

Out of 112 cases, three aspirates were inadequate and the remaining was adequately smeared. 11 histopathological specimens were available for cytopathological correlation.

Cytological interpretation:

Cytological diagnosis was made according to the IAC Yokohama reporting system. They were as follows, C1 in 3 cases (2.7%), C2 in 96 cases (85.7%), C3 in 3 cases (2.7%), C4 in 2 cases (1.8%), C5 in 8 cases (7.1%) Majority of the cases belonged to C2 category i.e. Benign lesions. (Figure 15)

IAC Category	No. of cases	Percentage
C1	3	3
C2	96	85
C3	3	3
C4	2	2
C5	8	7
Total	112	100

Table 3: Distribution of cases according to IAC criteria

The lesions which belonged to C2 included Fibroadenoma, Benign breast lesion, benign epithelial proliferative breast disease, breast abscess, breast mastitis, Fibrocystic disease, Galactocele, Granulomatous mastitis, Inflammatory breast disease. Among these Fibroadenoma was the most common diagnosis. C3 included hormone related changes with atypia and proliferative disease with atypia. C4 included suspicious favoring malignancy, and C5 included malignant carcinoma.

Eleven cases were available for histopathological correlation. Hence comparing with cytological diagnosis, the following discrepancies arrived. Two cases of fibroadenoma in histopathology were wrongly reported as proliferative breast disease and fibrocystic disease in cytology. All malignant cases in cytology also turned out to be malignant in histopathology.

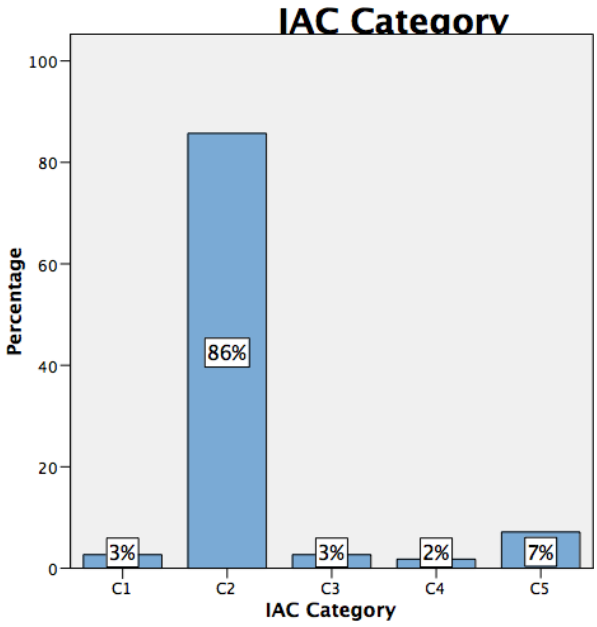

Figure 15: Bar diagram representing distribution of lesions according to IAC category

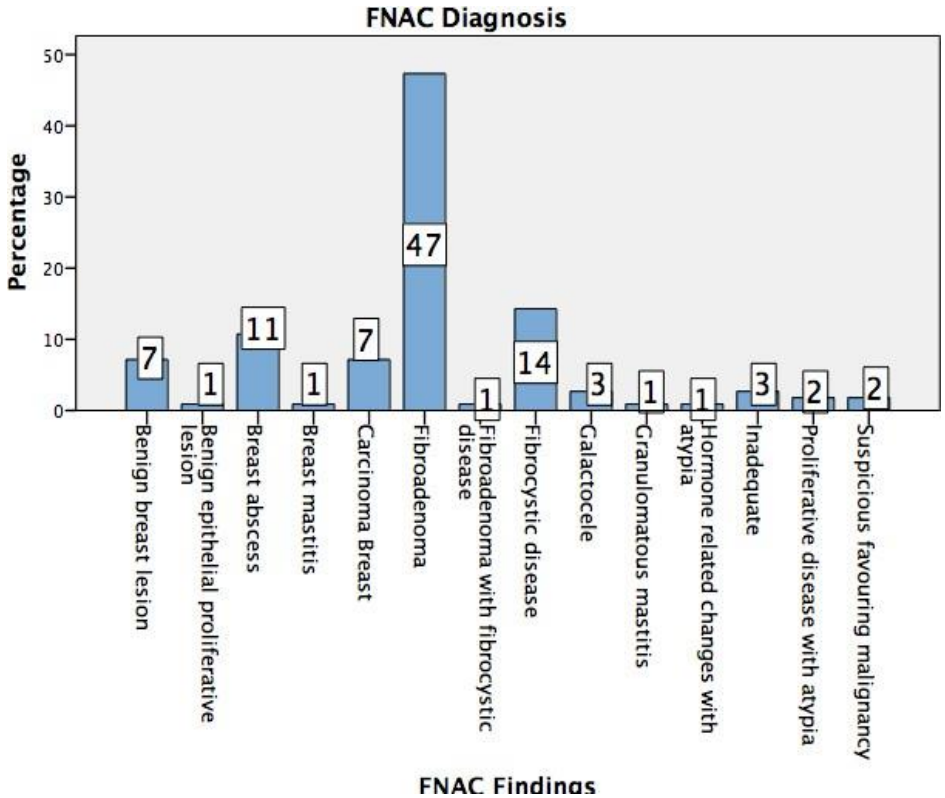

Figure 16: FNAC findings and their percentage

C1 Category:

Lesions under the C1 category represent Inadequate smear according to the IAC reporting system. In this study, 3 cases out of 112 were reported as inadequate. Two cases were from right breast and one from the left breast. The mass was located in lower outer quadrant in two cases and upper outer quadrant in one case. The consistency of the mass was soft in all three cases. Giemsa stain was used in all three cases, and the smears were poorly cellular (<6 clusters of epithelial cells) in a hemorrhagic background. Hence no opinion could be derived in these cases. Repeat aspirations was advised to these patients, but none had turned up.

C2 Category:

Lesions that are categorized under C2 are benign lesions. Out of 96 benign lesions, in 41 cases the mass was located in Upper outer quadrant. Sixteen cases in upper inner quadrants, 15 cases in lower outer, 19 cases in lower inner, 1 in the subareolar region, 4 cases were diffuse and seen in all quadrants. (Table 4)

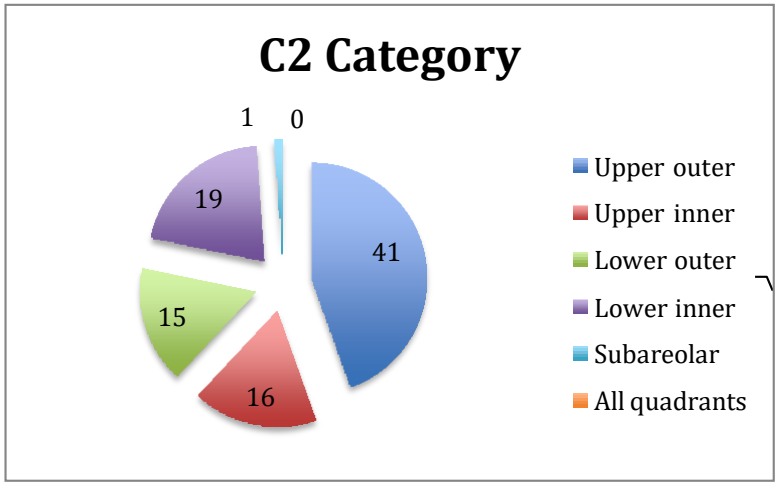

Figure 17: Anatomical distribution of C2 category lesions

Hence the most common anatomical distribution of the lesion is upper outer quadrant. (Figure 17)

Among these lesions, Breast abscess, Breast mastitis and granulomatous mastitis are grouped under inflammatory lesions.

Fibroadenoma:

Among the C2 category (Benign lesions), fibroadenoma was the most common with 53 cases. The mass was well defined in all the cases. Twenty one cases were located in the left breast, 28 cases in the right breast and 4 cases were bilateral. The consistency of the lesion was soft or soft to firm in almost all 53 cases. The smears from all the cases showed classical features of fibroadenoma. The diagnosis was made on the basis of following cytological features. The smears were highly cellular and arranged in closely packed clusters with bimodal population of benign ductal epithelial cells and myoepithelial cells arranged in staghorn pattern against a background of bare bipolar nuclei and stromal fragments. (Figure 18) Almost 34 aspirates showed predominantly branching staghorn pattern, eight aspirates showed monolayer sheets and the rest 11 cases showed both staghorn and monolayer sheet. Surgery was performed in 5 cases and they were in compliance with the FNAC finding.

C2 Category	**No. of cases**
Fibroadenoma	53
Benign breast lesion	8
Fibrocystic disease	16
Breast abscess	12
Breast mastitis	1
Granulomatous mastitis	1
Galactocele	3
Benign epithelial proliferative lesion	1
Fibroadenoma with fibrocystic disease	1
Total	**96**

Table 4: Category C2 and number of cases

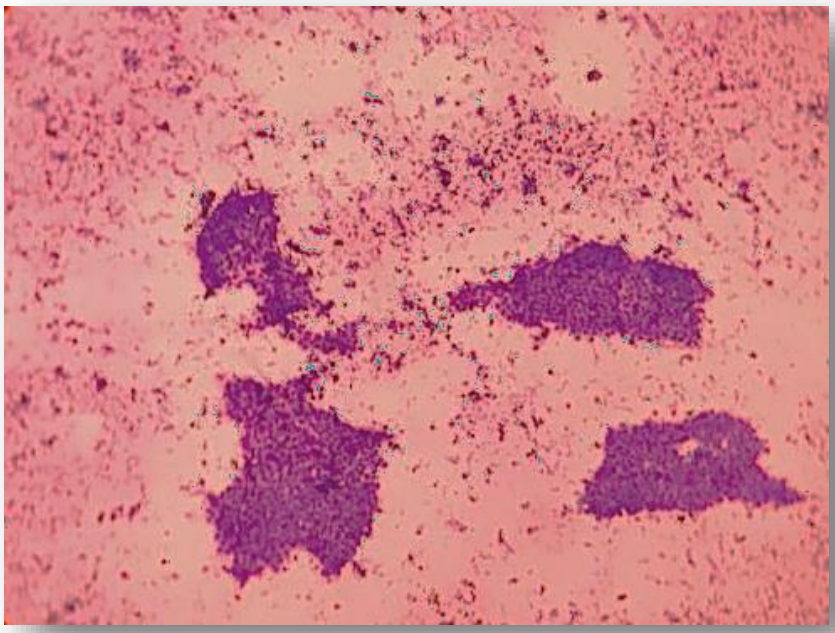

Figure18: Low power of Giemsa stained FNAC smear showing tightly cohesive epithelial cells in honey comb pattern (Fibroadenoma)

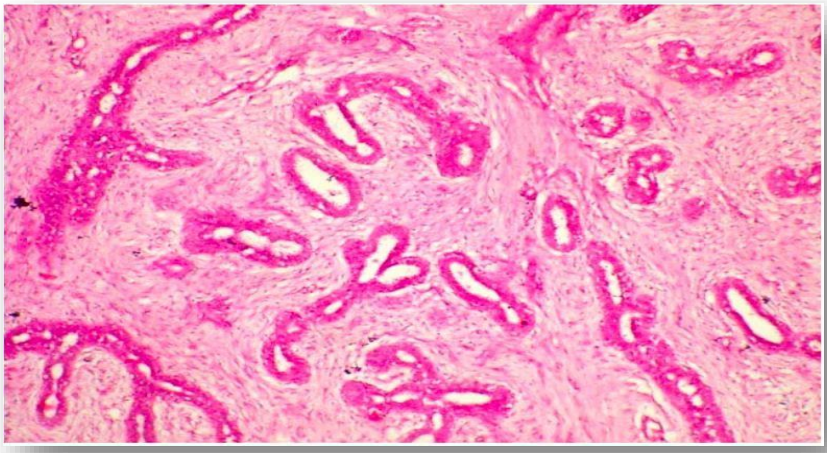

Figure 19: H & E stained sections showing intracanalicular and pericanalicular pattern (Fibroadenoma)

Inflammatory lesions:

Breast mastitis, breast abscess and granulomatous mastitis were grouped under this category. A total of 14 cases were reported.

Twelve cases presented with pain and/or mass in the breast, among which pain was the common symptom. The aspirate yielded pus like material in all the cases. The smear showed few ductal epithelial cells, stromal fragments and sheets of neutrophils.

A cytological diagnosis of breast abscess has been made.

One case with complaints of pain in breast, soft to firm in consistency was recorded. Aspirate again yielded pus like material. The smear showed a mixed population of inflammatory cells, predominantly of lymphocytes, followed by few neutrophils, plasma cells and macrophages. In few areas benign ductal epithelial cells were also observed. A cytological diagnosis of breast mastitis was given.

One case came with complaints of pain in breast, firm to hard in consistency. The smear showed groups of epithelioid cells, giant cells, plasma cells and lymphocytes with a few ductal epithelial cells in an inflammatory background. (Figure 20 & 21) AFB staining was done for the same, and final diagnosis was given as granulomatous mastitis.

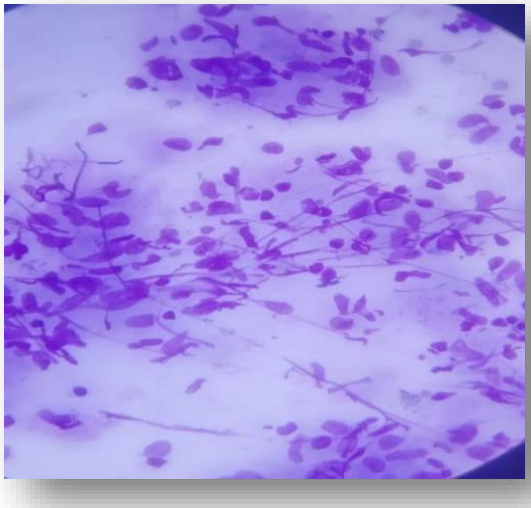

Figure 20

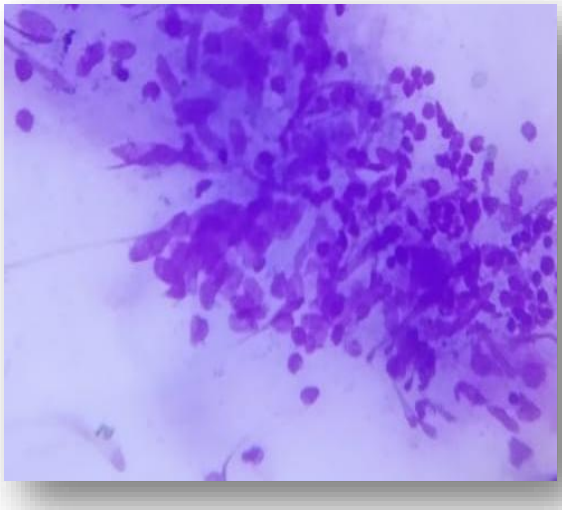

Figure 21

Figure 20 & 21: Giemsa stained smear showing granuloma formation composed of epithelioid cells, lymphocytes, necrosis (high power view)

Fibrocystic disease:

Sixteen cases with mass and pain in the breast were presented in the OPD. On examination the mass was soft to firm in consistency. The aspirate was bloody in nature. The size of the mass was reduced after aspiration. The cytological features showed few ductal epithelial cells, benign in nature in a background of variable amounts of cyst fluid, macrophages and also apocrine cells. With these features, a diagnosis of fibrocystic disease was given. (Figure 22)

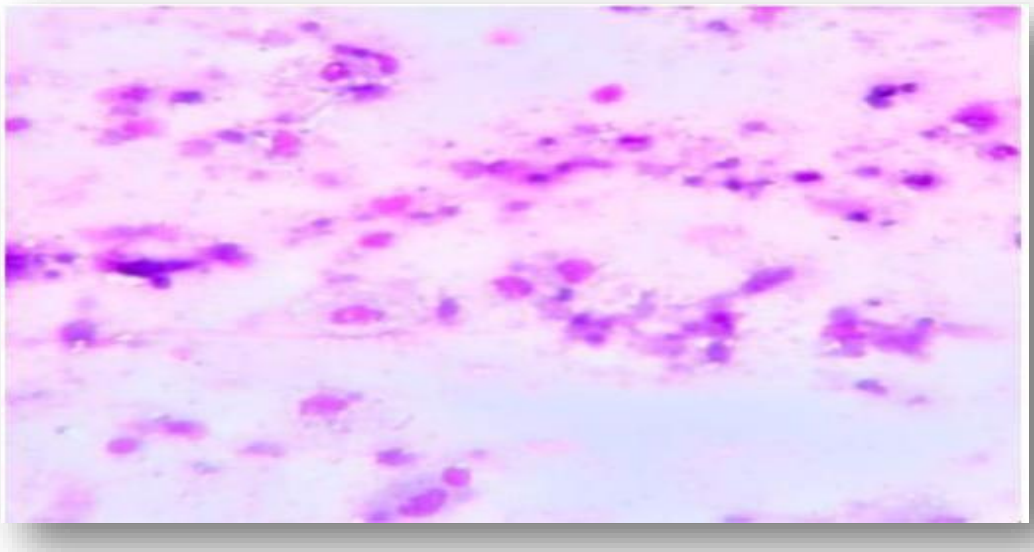

Figure 22: Giemsa stained smear showing macrophages, and apocrine cells in a cystic background (High power view)

Benign Epithelial Proliferative Lesion:

One patient presented with pain in breast. On palpation the lesion was firm in consistency. Aspiration was done and on microscopic examination, the following were the findings. Cellularity was moderate with few benign clusters of epithelial cells and myoepithelial cells arranged in sheets and one cluster showed a staghorn pattern. Few cyst macrophages were also seen in the background of bare bipolar nuclei. Thus as this case had features of both Fibroadenoma and Fibrocystic disease, a cytological diagnosis of benign epithelial proliferative lesion was given. One case on histological correlation was confirmed as Fibroadenoma.

Galactocele:

Three cases presented with pain in breast and history of lactation was present in two cases. Milk like aspirate was obtained. On microscopic examination, few inflammatory cells on a proteinaceous background were noted along with some necrotic debris. A cytological diagnosis of Galactocele was made.

Benign breast lesion:

Eight cases with complaints of mass and/or pain in the breast were reported. Pus like fluid was obtained on aspiration. The smears were moderately cellular with tightly packed clusters of ductal epithelial cells of benign nature on a background of bare

bipolar nuclei. Few myoepithelial cells were seen in some cases. Since these lesions presented with vague microscopic features, the diagnosis was given as benign breast lesion. One case was available for histopathological correlation, and was confirmed to be Fibroadenoma.

C3 category:

Three cases were categorized under C3 – Atypia probably benign. The patients were aged 33 to 44 years. The common presenting complaint was mass and/or pain in the breast. One case had a history of lactation. Two cases were located in the right breast and one in the left breast. The smears examined showed cohesive clusters of ductal epithelial cells and myoepithelial cells with very few/absence of bare bipolar nuclei. There were few clusters of epithelial cells that showed features of atypia in the form of mild nuclear pleomorphism, overlapping of nucleus, and prominent nucleoli in the clusters. In one case where lactational history was present, the diagnosis was given as hormone related changes with atypia. The diagnosis in the other two cases was given as proliferative disease with atypia. These patients were advised to follow up for surgery, but none turned up.

C4 category:

Two cases were included in this category- Suspicious, Probably in situ or invasive carcinoma. Both the lesions were seen in right breast and age of the patients was 48 and 55 years. The aspirate was bloody discharge. On microscopic examination, the smear was moderately cellular in one case and poorly cellular in another case. Most of the features of atypia were seen including nuclear pleomorphism, irregular nuclear membrane and presence of one or two nucleoli on a hemorrhagic background. However, a confirmatory diagnosis of malignancy cannot be derived as not all cells showed malignant features and adequacy criteria were not met. One case was followed up and histological correlation revealed a final diagnosis of Invasive ductal carcinoma with DCIS.

C5 category:

In this category of malignant lesion, eight cases were reported. Of 8 cases, the mass was located in the lower outer quadrant in 5 cases and in upper outer in 3 cases. Five cases involved the left breast and the other three were in the right breast. The age of the

patients ranged from 40 to 65 years. The FNAC smears were hypercellular, with loosely cohesive clusters and many single lying malignant ductal epithelial cells. Cells were enlarged with hyperchromatic nucleus; increased N:C ratio moderate to marked nuclear pleomorphism was seen along with coarse to granular to clumped chromatin with two or more prominent nucleoli and irregular nuclear margins. (Figure 23&24) A cytological diagnosis of Infiltrating Ductal Carcinoma (NOS) was given. Out of 8 cases, 4 cases were available for histological correlation and matched with cytological diagnosis in all three cases.

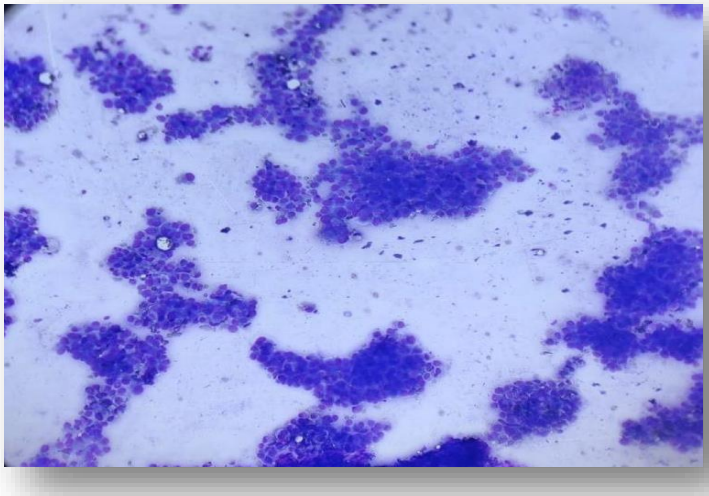

Figure 23: Giemsa stained FNAC showing hypercellular smear (scanner view)

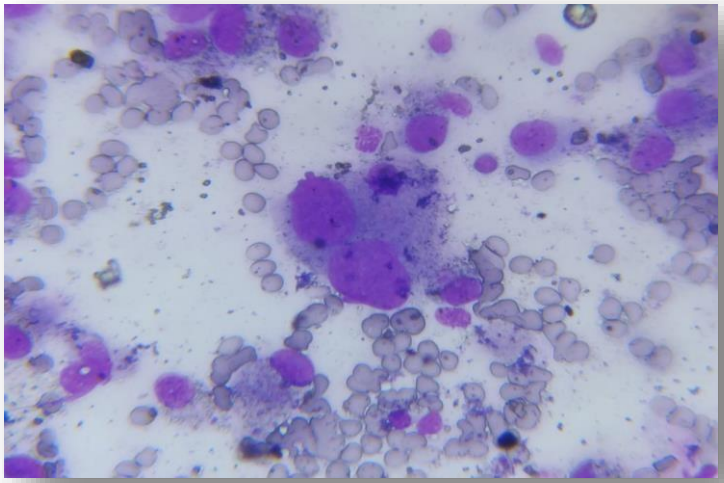

Figure 24: Giemsa stained FNAC smear showing large binucleate cell with scattered neoplastic cells in the background (high power view)

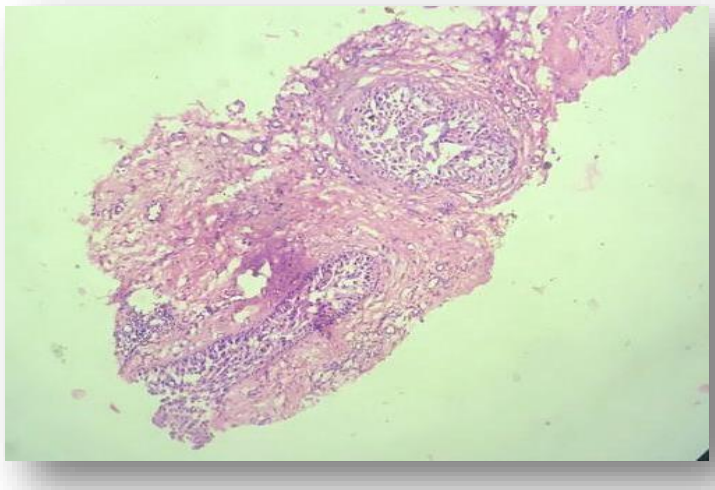

Figure 25: H & E stained section showing IDC with DCIS (scanner view)

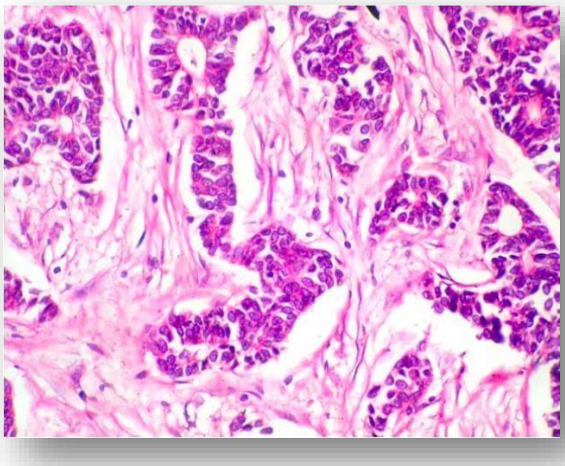

Figure 26: H&E stained section showing duct forming neoplastic cells (high power)

Statistical analysis:

Cytological diagnosis was correlated with histopathological diagnosis whenever possible in order to derive efficacy of FNAC.

Eleven cases out of 112 FNAC smears had histopathological correlation. With this available data for correlation, an overall sensitivity, positive predictive value was calculated.

Out of 11 biopsies done, following were the discrepancies in cytology. Two cases of fibroadenoma in histopathology were wrongly reported as proliferative breast disease

and fibrocystic disease in cytology.

The remaining 9 cases correlated with cytology diagnosis.

True Positive=9

False Positive=2

False Negative=0

Value	Formula	Percentage
Sensitivity	TP (9)/TP (9)+FN (0) x100	100
Positive predictive value	TP (9)/TP (9)+FP (2) x100	81.8

Table 5: Statistical analysis

Out of 11 biopsied cases, 4 cases diagnosed as malignant on cytology were confirmed to be malignant on histopathology as well. Thus making FNAC 100% sensitive and specific when it comes in diagnosing malignant lesions.

DISCUSSION

The present study included 112 FNAC smears of breast lesion, in which the cytomorphological features were analyzed in detail. The age of patients ranged from 13 to 75 years. Maximum number of patients was in the age group of 21 to 40 years. This correlated with the study conducted by Sarkar et al.[33] Out of 112 cases; most of the lesions were situated in the upper outer quadrant which was also seen in the study done by Ogbuanya et al. as well.[41]

The lesions were prevalent among married and parous females. The socioeconomic status of the patients was upper lower class. All these findings were in concordance with other literature as well.[33]

The FNAC results were categorized according to the IAC Yokohama reporting system into five categories (C1-C5). The present study showed most of the cases as benign lesions (96%), which was in concordance with the study conducted by Hemlata et al. in 2020, and Pandey et al in 2017. This may be because majority of the patients visiting our institution for breast FNAC belonged to a younger age group.

C1 Category- Inadequate:

Current study showed three inadequate cases (Category C1) out of 112 cases (2.7%) which was in concordance with studies done by David et al. (1.2%)[16], Sunita et al. (2.9%)[19], Arul et al. (2.7%)[42] and Hemlatha et al. (1.3%)[12]. Mostly in all the studies, the material was insufficient or the technique was poorly performed.

Studies	**C1 (%)**
David et al	1.2
Sunita et al	2.9
Arul et al	2.7
Hemlatha et al	1.3
Present study	2.7

Table 6: Comparison of C1 cases with other studies

C2 Category – Benign:

The lesions included in this category are fibroadenoma, inflammatory lesions (Breast abscess, Granulomatous mastitis, and Breast mastitis), Fibrocystic breast disease, benign epithelial proliferative lesion, Galactocele, and Benign breast lesions. The FNAC findings showed cellular smear with cells arranged in cohesive clusters, with a bimodal population of ductal epithelial cells and myoepithelial cells with bare bipolar nuclei in the background. There were 96(85.7%) cases in the C2 category in this study, among which Fibroadenoma was the majority of cases and this correlated with several other studies done by Gupta et al. (70.7%)[43], Agrawal et al. (65.3%)[35], Nargund et al. (65.38%)[44]and Sharif et al. (54%).[32]

Studies	**C2 (%)**
Gupta et al	70.7
Agrawal et al	65.3
Nargung et al	65.3
Sharif et al	54
Present study	85.7

Table 7: Comparison of C2 cases with other studies

C3 category – Atypia probably benign:

The lesions with FNAC findings showing cellular smear with cohesive clusters of bimodal population but showing mild atypia in the form of nuclear pleomorphism, overlapping of the nucleus, with prominent nucleoli in the clusters were categorized as C3. Three cases (2.7%) were reported, among which two were proliferative disease with atypia and one more case was reported as hormonal change with atypia as it had the lactation history. Menapara et al. (3.4%)[45] reported five cases with benign features but having nuclear atypia in this category and similarly Deshpande et al. reported 22(10.8%) cases in this category were all benign looking lesions with nuclear atypia were included.[46]

Studies	C3 (%)
Menapara et al	3.4
Despande et al	10.8
Present study	2.7

Table 8: Comparison of C3 cases with other studies

C4 category – Suspicious, probably In-situ or Invasive carcinoma:

Two cases (1.8%) showed moderate to poorly cellular smears showing features of atypia like nuclear pleomorphism, irregular nuclear membrane and presence of one or two nucleoli on a hemorrhagic background. Although most of the features of malignancies were seen, a definitive diagnosis of malignancy 'couldn't be derived, as not all cells showed malignant features and thus, the adequacy criteria was not met. Nigam et al. studied six cases (4.8%) and showed similar findings like highly cellular smears of epithelial tissue fragments in cribriform, micropapillary or papillary pattern of arrangement, heavily dispersed cells with mild-to-moderate nuclear atypia, reduced or absent myoepithelial cells. These insufficient cytomorphological malignant features were either due to lack in number or quality, which hinders a definitive diagnosis of malignancy.

C5 category – Malignant:

This category included 8 cases (7.1%). The findings on FNAC were hypercellular, with loosely cohesive clusters along with many single lying malignant ductal epithelial cells. There were enlarged cells with hyperchromatic nucleus, increased N:C ratio moderate to marked nuclear pleomorphism, prominent nucleoli, and irregular nuclear margins. Three cases out of these 8 cases were correlated with histopathology, and a diagnosis of Infiltrating Ductal carcinoma (IDC) was arrived. These findings were in concordance with other studies like Hemlata et al. where 19 cases (8.4%)[12] were diagnosed as malignant lesions which were later on correlated histopathologically and compared with Robinsons grading as well, majority of cases were diagnosed as IDC. Another study by Panjvani et al. also had a maximum number of IDC cases (29.2%)among the malignant lesions.[5]

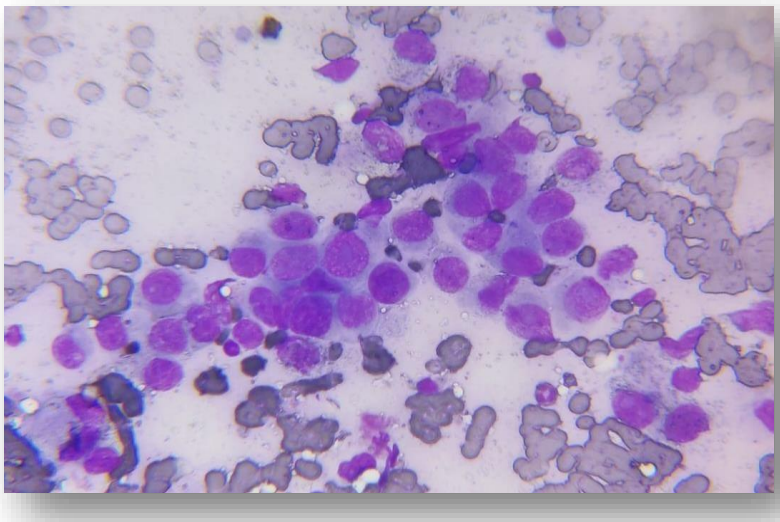

Figure 27: Loosely cohesive clusters of pleomorphic epithelial cells with irregular nuclei and prominent nucleoli (high power view)

Studies	**C5 (%)**
Hemlata et al	8.4
Panivani et al	29.2
Present study	7.1

Table 9: Comparison of C5 cases with other studies

Studies	Sensitivity (%)
Panivani et al	97.2
Ibikunle et al	99.4
Hemlata et al	100
Mohan et al	98.8
Aaisha et al	91.6%
Ogbuanya et al	90.4
Present study	100

Table 10: Comparison of sensitivity of FNAC among various other studies

Out of 112 cases, 11 cases were correlated histopathologically and the sensitivity of FNAC in diagnosing breast lesions was calculated. The present study showed 100% sensitivity and 81.8% positive predictive value. The 11 cases that were biopsied had 4 malignant cases that correlated with cytology findings. Hence by this study, it is derived that FNAC has 100% sensitivity when it comes to diagnosing a malignant breast lesion.

This statistical analysis was compared with other studies and the following observations were made.

CONCLUSION

As breast carcinoma is the leading cause of cancer causing death in females, the role of screening and timely diagnosis of the lesions are vital for the appropriate management of the patients. Although most of the breast lumps are benign as in this study most cases were under Category 2 (according to IAC system), the need to rule out malignancy is a must.

Fine Needle Aspiration Cytology has shown to be a simple, safe and cost effective method for the diagnosis and management of palpable breast lesions. This technique along with radiological and clinical assessment popularly known as 'Triple 'Assessment', has gained immense importance.

FNAC is performed on OPD basis using a disposable 10cc syringe with a very minimal complication. The accuracy of FNAC helps the clinician to decide on the treatment part. It thus helps the treating clinician arrive at a diagnosis with minimal expenditure of time and money and avoid unnecessary surgery to the patients.

Although FNAC has a lot of advantages, there are a few disadvantages where it is difficult for a pathologist to rule out the lesions which fall under the so called 'grey 'zone'. Hence for this reason, histopathological diagnosis remains the gold standard.
In the current era, steps for improving diagnostic accuracy are evolving with the help of advanced imaging techniques and immunological studies.

The majority of cases were benign in this study, which may be because of the locality of the tertiary care centre and major number of urban population as they have vast oppurtunities to gain awareness of breast carcinoma.

Along with diagnosis, the need for a universal standard of reporting is also gaining importance. This study has utilized International Academy of Cytology (IAC) system of reporting which has shown to provide hassle free reporting method.

The present study showed high sensitivity and positive predictive value of FNAC, especially in case of malignant lesions.

Hence FNAC is a well-established first line diagnostic test and also an effective tool for evaluating breast lesions. The standardized system of reporting has also allowed the pathologists to improve the reporting system globally and clinicians to arrive at a final diagnosis productively.

SUMMARY

An observational cross-sectional study was undertaken in the Department of Pathology, SANTOSH MEDICAL COLLEGE AND HOSPITAL, Ghaziabad, and Uttar Pradesh for a period of one year.

- FNAC was performed on 112 cases (female patients) for cytological assessment.
- The age range of the patients were 13 to 75 years with the mean age being 30 years.
- Majority were married females (79%) and porous (65%)
- There was majority of urban population that belonged to upper lower socio-economic status.
- The most common presenting complaints were mass/lump in breast (65%), followed by pain (15%).
- On examination, right breast was most commonly affected (51%) with involvement of upper outer quadrant (40%)
- The 112 cases were classified according to IAC standardized format of reporting system as C1-C5.
- C1-Inadequate, C2- Benign, C3- Atypia probably benign, C4- Suspicious, probably in-situ or invasive carcinoma, C5- Malignant.
- Out of 112 cases, majorities were in C2 (85%) i.e. benign lesions.
- Fibroadenoma was the most common among the benign lesions of about 53 cases.

  Eleven cases were available for histopathological correlation on comparison with cytological findings, two discrepancies were derived.
- Two cases of fibroadenoma were wrongly reported as proliferative breast disease and fibrocystic disease in cytology. Although all malignant cases in cytology came out to be malignant in histopathology as well.
- Thus, when comes to diagnosis of malignant lesions, FNAC showed 100% correlation with histopathological finding.

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Annexure I

PLAGIARISM CERTIFICATE

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Document Information

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nnexure II

STUDY PROFORMA

1) Serial No :
2) Date :
3) FNAC NO. :
4) Department :
5) Name :
6) Age :
7) Residency : Urban/Rural
8) Marital Status : Married/Single
9) Parity :
10) Lactation History :
11) Chief complaints : Lump in Breast (Right/Left) / Pain / Nipple discharge / Heaviness / Nipple & areola changes / Fever / Others
12) Duration of Lump in breast (in days):
13) Past History :
14) Family History:
15) Provisional Diagnosis :
16) Local examination of Breast lump:
    a. Site
    b. Size
    c. Consistency: Soft / Firm / Hard
    d. Local temperature : Normal / Raised
    e. Tenderness
    f. Color of the skin
    g. Nipple & Areola
    h. Mobility
    i. Nipple discharge
17) Local examination of Contralateral Breast:
18) Local examination of Lymph Node:
19) Fine Needle Aspiration Cytology:
    a. Date of aspiration :
    b. Visual appearance : Clear / Bloody / Pus-filled / Others
    c. Sample adequacy : Adequate / Inadequate
    d. Cellularity : Cellular / Hypocellular / Hypercellular

e. Pattern: Sheets / Clusters / Single / Papillary / Glandular / Loosely Cohesive / Tightly Cohesive
f. Background: Hemorrhagic / Necrotic / Mucinous / Dirty / Proteinaceous
g. Others:
h. Impression:

20) Histopathological Diagnosis (if available):

Annexure III

STATISTICAL ANALYSIS

Statistical software used: R software version 4.0.2

Statistical test applied.

Descriptive statistics like mean, percentage and standard deviation were used.

Chi-Square test of significance was used.

The results were expressed in the form of bar diagrams, pie charts and pictographs and compared with other similar studies done in the past as well as with newer studies.

Annexure IV

STAINING PROCEDURE

Giemsa Stain:

It is one of the most common Romanowsky stains used in cytology.

Storage:

It should be protected from light and temperature should be kept at around 25°C. Reagents that are not opened may be used until the expiry date provided on the label.

Reagents:

Giemsa powder
Methanol
Glycerin
Water

Preparation of giemsa stock solutions:

- Prepared by dissolving 3.8gm Giemsa powder in 250 ml methanol.
- Heating the solution at around 60 degrees.
- Slowly 250 ml glycerin is added.
- The solution prepared is filtered and left to stand for one to two months before usage.

Preparation of giemsa working solutions:

Prepared by mixing 80 ml of distilled water 10 ml methanol and 10 ml stock solution

Staining method:

1. Fixation of the air-dried smear in methanol for around 5 minutes
2. Next step is to flood the slide with Giemsa solution for around 20 minutes
3. The slides are then washed with clean water for 5 minutes
4. The slides are dried in upright position at room temperature
5. Mounting of the slides can be done with the coverslip using DPX

Precautions:

- Specimens should not dry at any stage of the procedure.
- Proper washing is required to avoid dye artifacts.
- For washing buffered water is recommended as proper staining result is Dependent on the ph. Whereas alkaline pH increases blue, acidic pH gives pink or reddish tinge to the stained smear.

Hematoxylin & Eosin stain:

Hematoxylin solutions are nuclear stains intended for use in Histology and Cytology.Hematoxylin, a common nuclear stain, is isolated from an extract of logwood (Haematoxylon campechianum). Before hematoxylin can be used as a nuclear stain, it must be oxidized to hematein and combined with a metallic ion (mordant). Most successful mordants have been salts of aluminum or iron.

Reagents:

Hematoxylin – 2g/dl
Sodium iodate – 0.2g/dl
Aluminum sulfate - 17.6 g/l
Stabilizers

Procedure:

1. Deparaffinize to water or fix and dehydrate frozen sections.
2. Stain in Hematoxylin Solution for 1.5-3 minutes
3. Tap under water wash.
4. Differentiation Solution for 20-60 seconds
5. Tap water wash.
6. Blue in 'Scott's Tap Water Substitute for 5-60 seconds

7. Tap water wash.
8. Counterstain:

-Papanicolaou Stain OG-6, And

-Papanicolaou Stain EA 50,

-Or Papanicolaou Stain EA 65, Or

- Papanicolaou Stain, Modified EA for 1-3 minutes

9. Dehydrate, clear and mount

Precautions:

The timings will vary and the can be adjusted to suit personal preferences.
Stain solutions, which are heavily used, will lose their staining powers and the staining times should be lengthened or new solutions should be used.
Some tap water supplies are acidic and unsuitable for use in the ""blueing"" portion of this procedure.
If tap water is acidic, use a dilute alkaline solution.
Purple or red-brown nuclei are indicative of inadequate ""blueing"".

Annexure V

MASTER CHART

S.No	FNAC No.	Name	Age	MaritalStatus	Residency	Socio-economic class	Parity	Chief Complaints	Duration (in days)	Side	Consistency	Anatomical quadrant	FNAC Diagnosis	IAC Category	Histopathological diagnosis
1	F-81145	Shikha	14	S	U	Upper lower	N	Mass	60	L	Firm	Upper outer	Fibroadenoma	C2	NA
2	F-81149	Sneha Suman	18	S	U	Upper lower	N	Mass	30	L	Firm	Upper outer	Fibroadenoma	C2	NA
3	F-81158	Pooja	21	S	U	Upper lower	N	Mass	90	L	Soft	Lower outer	Fibroadenoma	C2	Fibroadenoma
4	F-81163	Anurekha	34	M	U	Lower middle	P	Pain	14	L	Soft	Subareolar	Breast abscess	C2	NA
5	F-81167	Arti	18	S	U	Upper middle	N	Mass	120	R	Soft	Upper outer	Fibroadenoma	C2	NA
6	F-81172	Shru Sharma	40	M	R	Upper lower	P	Mass & Pain	10	R	Firm to hard	Lower Inner	Proliferativedisease with atypia	C3	NA
7	F-81178	Aanchal	17	S	U	Upper lower	N	Mass	60	R	Firm	Upper outer	Fibroadenoma	C2	NA
8	F-81179	Anjana	42	M	U	Lower middle	P	Mass	30	L	Soft to firm	Upper outer	Fibroadenoma	C2	NA
9	F-81180	Komal	33	M	U	Upper lower	P	Mass	15	R	Soft	Lower outer	Inadequate	C1	NA
10	F-81182	Usha Devi	40	M	U	Upper lower	P	Mass	12	R	Soft to firm	Upper outer	Benign breast lesion	C2	NA
11	F-81188	Rabiya	25	M	U	Upper middle	N	Mass	20	L	Soft	Upper outer	Benign breast lesion	C2	NA
12	F-81192	Sonia	20	M	U	Lower middle	N	Mass	60	R	Firm	Lower Inner	Fibroadenoma	C2	NA
13	F-81199	Pinky	19	S	U	Upper lower	N	Mass	30	L	Firm	Upper outer	Fibroadenoma	C2	NA
14	F-81204	Shikha	16	S	U	Upper lower	N	Mass	15	L	Soft to firm	Upper outer	Fibroadenoma	C2	NA
15	F-81216	Jyoti	18	S	U	Upper lower	N	Mass	60	R	Firm	Upper outer	Fibroadenoma	C2	NA
16	F-81218	Suman	43	M	U	Upper lower	P	Pain	7	L	Soft	Lower Inner	Fibrocystic disease	C2	NA
17	F-81232	Sajida	35	M	U	Upper lower	P	Mass	60	R	Soft to firm	Lower outer	Fibroadenoma	C2	NA
18	F-81233	Laxmi	27	S	U	Lower middle	N	Mass & Pain	5	L	Tender	Upper outer	Breast abscess	C2	NA
19	F-81246	Kavita	30	M	U	Lower middle	N	Mass	90	L	Firm	Lower outer	Fibroadenoma	C2	NA
20	F-912	Raki	20	M	U	Lower middle	N	Mass	60	R	Soft to firm	Upper outer	Fibroadenoma	C2	NA
21	F - 915	Sumita	36	M	U	Upper lower	P	Mass	15	R	Soft	All quadrants	Fibrocystic disease	C2	NA
22	F - 9119	Mubasharen	35	M	R	Upper lower	P	Pain	5	L	Firm	Upper Inner	Benign epithelial proliferative brea	C2	Fibroadenoma
23	F - 9122	Geetanjali	26	M	U	Lower middle	N	Mass & Pain	10	R	Tender	Upper Inner	Breast abscess	C2	NA
24	F - 9150	Vinayku Yada	18	S	U	Upper lower	N	Mass & Pain	30	R	Firm to hard	Lower outer	Fibroadenoma	C2	NA
25	F - 9153	Hemalatha	25	M	U	Lower middle	P	Mass	60	L	Soft	Lower outer	Benign breast lesion	C2	NA
26	F - 9157	Parveen	17	S	U	Lower middle	N	Mass	60	L	Soft to firm	Upper Inner	Benign breast lesion	C2	NA
27	F - 9163	Payal	18	M	U	Lower middle	N	Mass	30	R	Firm	Lower outer	Fibroadenoma	C2	NA
28	F - 9180	Raj Kumari	40	M	U	Upper lower	P	Mass & Pain	365	R	Hard	Lower outer	Carcinoma Breast	C5	NA
29	F- 9181	Sakshi	24	M	U	Upper lower	P	Mass	40	R	Firm	Upper outer	Fibroadenoma	C2	Fibroadenoma
30	F- 9184	Shushila	50	M	R	Upper middle	P	Pain	12	R	Soft	Upper Inner	Breast abscess	C2	NA
31	F- 9189	Shivani	13	S	U	Lower middle	N	Mass	30	R	Firm	Lower Inner	Fibroadenoma	C2	NA
32	F - 9197	Pinki	22	M	U	Upper lower	N	Mass	160	R	Soft to firm	Lower Inner	Fibroadenoma	C2	NA
33	F - 91103	Golida	27	M	U	Upper lower	P	Pain & Warm	3	L		Upper outer	Breast mastitis	C2	NA
34	F - 91105	Pooja Mohra	20	M	U	Lower middle	N	Mass	30	L	Soft	Lower Inner	Fibroadenoma	C2	NA
35	F-91116	Shally sharma	30	M	U	Upper lower	P	Pain & Warm	14	R		Upper outer	Galactocele	C2	NA
36	F- 91118	Shushila	50	M	U	Lower middle	P	Pain & Warm	12	R		Upper Inner	Breast abscess	C2	NA
37	F - 91133	Seema	44	M	U	Lower middle	P	Mass	60	R	Soft to firm	Upper Inner	Proliferative disease with atypia	C3	NA
38	F 91141	Suman	27	M	U	Upper lower	P	Mass	30	R	Soft	Upper outer	Inadequate	C1	NA
39	F - 91147	Sonika singh	20	S	U	Lower middle	N	Mass	20	L	Firm	Lower outer	Fibroadenoma	C2	NA
40	F - 91155	Meera	28	M	U	Upper lower	P	Mass	90	R	Soft to firm	Lower Inner	Fibroadenoma	C2	NA
41	F - 91159	Rakhi	22	M	U	Upper lower	P	Mass	7	R	Firm	Upper outer	Fibroadenoma	C2	Fibroadenoma
42	F- 91160	Malini	25	M	U	Lower middle	P	Mass	5	L	Firm	Lower outer	Fibroadenoma	C2	NA
43	F - 91164	lalla Bai	40	M	U	Upper lower	P	Mass & Pain	280	L	Hard	Lower outer	Carcinoma Breast	C5	IDC
44	F - 91168	Deepika	35	M	U	Upper lower	P	Mass	30	R	Soft to firm	Lower Inner	Fibroadenoma	C2	NA
45	F - 91170	Sanju	17	S	U	Lower middle	N	Mass	60	L	Soft	Upper outer	Fibroadenoma	C2	NA
46	F- 91171.	Laxmi	75	M	U	Upper lower	P	Pain	15	L		Upper Inner	Breast abscess	C2	NA
47	F - 91173	Pinki	32	M	R	Upper lower	P	Pain	12	R		Upper Inner	Breast abscess	C2	NA
48	F - 91196	Santosh Devi	34	M	U	Upper lower	P	Mass	20	L	Soft to firm	Upper outer	Benign breast lesion	C2	NA
49	F - 91199	Shashi	30	M	U	Upper lower	P	Mass	30	R	Firm	Upper outer	Fibroadenoma	C2	Fibroadenoma
50	F - 91204	Asma	25	M	U	Upper lower	P	Pain	3	R	Soft	Upper outer	Breast abscess	C2	NA
51	F - 91205	Prinki	19	M	U	Lower middle	N	Mass	90	R	Firm to hard	Upper outer	Fibroadenoma	C2	NA
52	F- 91206	Preeti	31	M	U	Lower middle	P	Mass	30	L	Firm	Upper outer	Fibroadenoma	C2	NA
53	F - 91212	Meena	32	M	U	Upper middle	P	Mass	20	R	Soft to firm	Upper outer	Benign breast lesion	C2	NA
54	F - 91213	Anita	36	M	U	Upper lower	P	Mass & Pain	12	R	Firm to hard	Upper outer	Fibrocystic disease	C2	NA
55	F - 91215	Rahat	23	M	U	Upper lower	P	Mass	60	L	Soft to firm	Lower Inner	Benign breast lesion	C2	NA
56	F - 91217	Veena Shrini	39	M	U	Upper lower	P	Mass	30	L	Firm	Lower outer	Fibroadenoma	C2	Fibroadenoma
57	F - 91218	Bany	35	M	U	Upper lower	P	Mass & Pain	10	R	Firm	Upper Inner	Fibrocystic disease	C2	NA
58	F- 91227	Munni devi	62	M	U	Upper lower	P	Mass & Pain	320	R	Hard	Lower outer	Carcinoma Breast	C5	NA
59	F - 91234	Tanisha	17	S	U	Upper lower	N	Mass	120	R	Firm	Lower Inner	Fibroadenoma	C2	NA

59	F - 91234	Tanisha	17	S	U	Upper lower	N	Mass	120	R	Firm	Lower Inner	Fibroadenoma	C2	NA
60	F - 91236	mamta	45	M	R	Upper lower	P	Mass	15	L	Firm	Upper Inner	Fibrocystic disease	C2	NA
61	F - 91243	Swati sharma	16	S	U	Upper lower	N	Mass	30	R	Soft	Lower outer	Fibroadenoma	C2	NA
62	F- 91248	Snelatha	25	M	U	Upper lower	P	Mass & Pain	60	R	Soft to firm	Lower Inner	Fibroadenoma	C2	NA
63	F - 91254	Nandhi Sharn	21	M	U	Upper lower	P	Mass	15	L	Soft	Lower Inner	Fibroadenoma	C2	NA
64	F - 91268	Meeta Devi	35	M	U	Upper lower	P	Mass	14	L	Firm	Upper Inner	Fibrocystic disease	C2	NA
65	F - 91271	Bachahan De	65	M	U	Lower	P	Nipple discha	730	L	Hard	Lower outer	Carcinoma Breast	C5	NA
66	F - 91274	Chetna	20	S	U	Lower middle	N	Pain & Warm	14	R	Firm to hard	Lower outer	Granulomatous mastitis	C2	NA
67	F - 91276	Niketa	29	M	U	Upper lower	P	Pain & Warm	10	L	Soft to firm	Lower Inner	Galactocele	C2	NA
68	F - 027	Sushma	50	M	U	Upper lower	P	Nipple retrac	1095	L	Hard	Upper outer	Carcinoma Breast	C5	NA
69	F - 0216	Farahana	25	M	U	Lower middle	N	Pain	12	R		Upper Inner	Breast abscess	C2	NA
70	F - 0227	Neelam Mish	40	M	U	Upper lower	P	Mass	60	L	Soft	All quadrants	Fibroadenoma	C2	NA
71	F - 0263	Priyasharma	22	M	U	Upper lower	N	Mass	30	L	Soft to firm	Lower outer	Fibroadenoma	C2	NA
72	F - 0270	Rajbandhu	60	M	U	Lower middle	P	Mass & Pain	12	L	Firm	Upper Inner	Fibrocystic disease	C2	NA
73	F - 0274	Sudesh	33	M	U	Lower middle	P	Mass & Pain	10	R	Soft to firm	Upper outer	Fibrocystic disease	C2	NA
74	F - 0281	Munni	45	M	R	Upper lower	P	Mass	60	L	Firm	Upper Inner	Fibroadenoma with fibrocystic dise	C2	Fibroadenoma
75	F - 0283	Mikta	19	M	U	Upper lower	P	Mass	40	L	Firm	Lower Inner	Fibrocystic disease	C2	NA
76	F-0287	Archana	22	M	U	Lower middle	P	Pain	15	R	Soft	All quadrants	Breast abscess	C2	NA
77	F-1297	Pooja Verma	27	M	U	Upper lower	P	Mass	30	R	Soft to firm	Lower Inner	Fibroadenoma	C2	NA
78	F-1201	Neha	21	S	U	Upper lower	N	Mass	20	L	Soft	Lower Inner	Fibroadenoma	C2	NA
79	F-1234	Shashi Bala	34	M	U	Upper lower	P	Pain & Warm	14	R	Soft	Upper outer	Breast abscess	C2	NA
80	F-1227	Geetha	62	M	U	Upper lower	P	Mass & Pain	240	L	Hard	Upper outer	Carcinoma Breast	C5	NA
81	F-1236	Khushboo	17	S	U	Upper lower	N	Mass	30	R	Soft	Lower Inner	Fibroadenoma	C2	NA
82	F-1247	Preeti	33	M	U	Upper lower	P	Pain	7	L	Firm to hard	Lower Inner	Hormone related changes with aty	C3	NA
83	F-1251	Sumithra	60	M	U	Upper lower	P	Mass	365	R	Hard	Upper outer	Carcinoma Breast	C5	IDC
84	F-1240	Baby Shabna	13	S	U	Upper lower	N	Mass	15	R	Soft	Lower outer	Fibroadenoma	C2	NA
85	F-1267	Babli	49	M	U	Lower middle	P	Mass	30	L	Soft to firm	Upper outer	Fibrocystic disease	C2	NA
86	F-1293	Parveen	23	M	U	Lower middle	P	Nipple discha	3	L	Firm	Lower outer	Galactocele	C2	NA
87	F-12100	Manisha	27	M	U	Upper lower	P	Mass	20	B/L	Soft	Lower outer	Fibroadenoma	C2	NA
88	F-12105	Mamta	28	M	U	Upper lower	P	Mass	30	L	Firm	Upper Inner	Fibroadenoma	C2	NA
89	F-12116	Omphal Jain	74	M	U	Lower middle	P	Mass & Pain	14	L		Upper outer	Breast abscess	C2	NA
90	F-12121	Shuk Devi	60	M	R	Upper lower	P	Mass	10	R	Firm	Upper outer	Fibrocystic disease	C2	NA
91	F-12125	Rajini Gupta	48	M	U	Upper lower	P	Mass	160	R	Firm to hard	Lower outer	Suspicious favouring malignancy	C4	NA
92	F-12126	Manisha	19	M	U	Upper lower	N	Mass	60	R	Soft	Upper Inner	Fibroadenoma	C2	NA
93	F-12132	Poonam	32	M	U	Lower middle	P	Mass	20	R	Soft	Upper outer	Fibroadenoma	C2	NA
94	F-12137	Nisha Pandey	31	M	U	Upper lower	P	Mass	10	L	Soft to firm	Lower Inner	Fibrocystic disease	C2	NA
95	F-12144	Krisha	19	S	U	Upper lower	N	Mass	30	L	Soft	Upper outer	Fibroadenoma	C2	NA
96	F-2276	Bhawana	20	S	U	Lower middle	N	Mass	60	L	Firm	Lower Inner	Fibroadenoma	C2	NA
97	F-2278	Renu	33	M	U	Upper lower	P	Mass	90	R	Firm	Upper outer	Fibroadenoma	C2	NA
98	F-2273	Seema Panch	36	M	U	Upper lower	P	Pain	12	B/L	Soft to firm	Lower Inner	Fibrocystic disease	C2	NA
99	F-2274	Muneshi	50	M	R	Upper lower	N	Pain	30	L	Soft	Lower outer	Inadequate	C1	NA
100	F-2271	Varsha	23	M	U	Upper lower	N	Mass	30	R	Firm	Upper outer	Fibroadenoma	C2	NA
101	F-2269	Poonam	30	M	U	Upper lower	P	Mass	60	R	Soft to firm	Upper outer	Fibrocystic disease	C2	NA
102	F-2247	Kumkum	51	M	U	Lower middle	N	Mass	30	B/L	Soft	Upper outer	Fibroadenoma	C2	NA
103	F-2248	Alfiya	18	M	U	Upper lower	P	Mass	7	R	Firm	Upper outer	Fibroadenoma	C2	NA
104	F-2232	Alka	28	M	U	Lower middle	P	Mass	30	B/L	Firm	Upper outer	Fibroadenoma	C2	NA
105	F-2250	Omnali	35	M	U	Upper lower	N	Pain	15	R	Soft to firm	Upper outer	Fibrocystic disease	C2	NA
106	F-2288	Soni	30	M	U	Upper lower	P	Mass	40	B/L	Firm	Upper outer	Fibroadenoma	C2	NA
107	F-2272	Reena	20	S	U	Lower middle	N	Mass	30	R	Firm	Upper Inner	Benign breast lesion	C2	NA
108	F-2295	Meenakshi	44	M	U	Upper lower	P	Mass	30	R	Firm	Upper outer	Fibroadenoma	C2	NA
109	F-22108	Anu	32	M	U	Lower middle	P	Mass & Pain	10	L	Soft to firm	All quadrants	Fibrocystic disease	C2	NA
110	F-22127	Latha	26	M	U	Upper lower	P	Mass	20	L	Soft	Upper outer	Fibroadenoma	C2	NA
111	F-22130	Usha	55	M	U	Lower middle	P	Mass & Pain	7	R	Firm to hard	Lower outer	Suspicious favouring malignancy	C4	IDC with DCIS
112	F-22134	Raj Kumari	55	M	U	Upper lower	P	Mass & Pain	90	L	Hard	Lower outer	Carcinoma Breast	C5	IDC

Annexure VI

CONSENT FORM

रोगी का सहमति पत्र

मैं.....उम्र ··.....साल, ... का / की माता / पिता ;

निवासी.....

.....अपनी स्वेछा से चिकित्सीय अध्ययन में अपने पुत्र / पुत्री को सम्मिलित करने की सहमति प्रदान करता / करती हूं। मुझे सेवा प्रदान करने वाले चिकित्सक ने संतुष्टि की सीमा तक इस चिकित्सीय अध्ययन की प्रकृति व उद्देश्य भली भांति अवगत करा दिया है। मैं समय पर अपने पुत्र / पुत्री कि जांच के लिए सहमति देता / देती हूं।

चिकित्सक के हस्ताक्षर।

रोगी के माता/पिता के हस्ताक्षर

अथवा अंगूठे का निशान

नाम :

पता :

फ़ोन क्रमांक :

दिनांक :